# EPA Jacket 71297-1 Vol.1

Receip for Section 3	
S: 775997  Regulatory Type: Product Registration - Section 3	
	Yes C No.
Company: 71287 AGRO FRESH MC.	
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 81	
Product #: 71297-1 Product Name: ETHYLPLOC	
Me Too Section3:  Me Too Product Name:	
Application Date: 10-Mar-2005 PP Rec'vd Date: 11-Mar-2005	Receipt Content
Front End Date: 11-Mar-2005 Risk Manager Send Date: 18-Mar-2005	iel iel
Fast Track: New Ingredient	
Receipt Description:	
MAR 1 6 2005 BPEP	to lings dient
rm → Form 5	Signature Date

to ge

MAR 2 A 2005

018' 10 332 Rollard

> A IO HATI 18 2005 Polh

S: 785812		Dulant Latter
Regulatory Type: Product Registration	- Section 3	
Application Type: Amendment	C Yes C N	Enter More Informatio
Company: 712/7 AGRO FR	BH INC.	
Risk Manager: Biologicals & Poliution	n Prevention Division, PM Team 91	<u> </u>
Product #: 71297-1 Pro	duct Name: THYLBUCC	
Me Too Section3:	Me Too Product Name:	
Application Date: 06-Aug-2004	OPP Rec'vd Date: 27-Aug-2004 in	Receipt Content
Front End Date: 27-Aug-2004	Risk Manager Send Date: 27-Aug-2004	
Fast Track:	™ Ing:	
Receipt Description:	The second secon	
	AUG 3 0 2004 PPRO	the land
	AUG 3 0 2004	DAME -
h-1 [ mmo+(0	18 □	14 200

301 FTT (100)

766612 300 ND 17

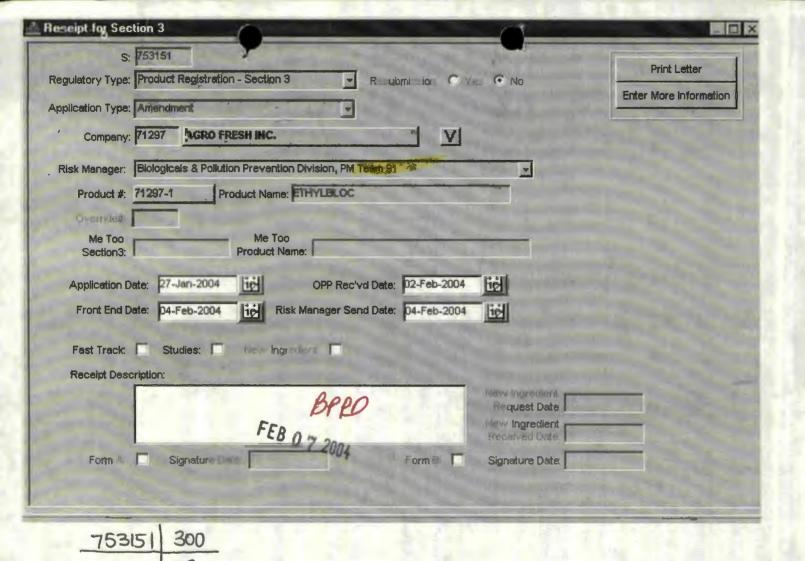
> AIO SEP 3 2004 Sd3

### Tox QuikSheet®

Product Name: EPA File Symbol/ Reg. #: 71297-1			4			
A.I.: 1-Methylayelopten	Code		Label Sig	gnal Word:	CAUGIOVI	_
Acute Toxicity	Tox Cat.	Test Substanc		onal Inf	Cormation*  Source (e.g. DBR, BRAD)	
Oral Toxicity/ Pathogenicity	IV	Circle One EP TGAI	AI	SPR	PED	
Dermal Toxicity/ Pathogenicity	111	EP TGAI	AI			
Inhalation/ Pulmonary Toxicity	17	EP TGAI	AI			
Primary Dermal Irritation/ Pathogenicity	IV	EP TGAI	AI			
Primary Eye Irritation/ Pathogenicity	111	EP TGAI	AI			
Hypersensitivity	Circle One —	EP TGAI	AI	V	4	
Tissuo culturo (viruse only)		EP TGAI	AI			
Comments:						
			To	day's Da	ite: 15 Sep 2004	

Last Name, First Initial: Duggard, M

4



JUL 14 2004 SOLL

# REGISTRATION CHRONOLOGY

Action Code .	Record No./ Ref. No.	Event	Response Code
	71297-1		
305	5609100	86-5 failire. Ltr sent.	38
		V	
	44		
	•		
I FAI			
	Value o e		
*8 *			
1	* • •		
			1
			/
. ,			- 7
	11		_
1			
å0 *			
-			
	- **		
•			
•			
	- colqui		•
		312	
-			
	•		

epilos

## FBPPD PRAT ACTION CODING FORM

REGISTRANT/COMPANY NAME:		Fast Tr	ack: Yes No
ROHM HAAS			ed by LH
EPA REG./FILE SYMBOL 712-9-1	7-1	[Note: I] need to	f Fast Track, you may change Reviewer's n PRAT.]
	٦,	IAGHIE I	
(New A.I/EUP'S/Tolerances: Yes□ No□	•		
DATE OF APPLICATION 12 13 0	t.	Tilled	! 86-5
EPA RECEIVED DATE 171401	t		ïi
BPPD RECEIVED DATE 12201			
SUBMISSION BARCODE S 6 1910	6	. 7	
ASSIGNED IN PRAT: Yes No DATE	1.24.02		
LOGGED IN BRATS: Yes□ No□ DATE	1 1	LETED BY	CP
	1/30/02		
***	4,4,4,4,4,4,4,4	y dy dy dyd	يع علي علي علي علي علي علي علي علي
FINAL ACTION			
RESPONSE CODE: 38			
RESPONSE DATE: 2/6/02			
MOS:(1) Cite All(4) Not Applicable(8) Selective	CRP Restricted Use: Manufacturing Use: Exclusive Use:	Yes \bigcap Yes \bigcap Yes \bigcap Yes \bigcap	No

BPPD PRAT ACTION CODING FORM PM 90: Janet Andersen REVIEWER: (ASSIGNED BY: EPA REG./FILE SYMBOL 71297-ACTION CODE 350 (NEW a.i./EUPs/Tolerances: Yes \_\_\_\_/No\_\_\_) SUBMISSION BARCODE \$590969 DATE ON APPLICATION 11-15-00 EPA RECEIVED DATE 11-20-00 PM RECEIVED DATE 11-20-00 ASSIGNED IN PRAT: YES X NO\_\_\_\_ COMPLETED BY: All DATE: FINAL ACTION Drie Return, facket to Response Date: MOS: (1) Cite-All (4) Not Applicable (8) Selective Yes No CRP: Yes\_\_\_\_ No\_\_\_ Restricted Use: Yes\_\_\_\_No\_\_\_ Manufacturing Use:

No

Yes

Exclusive Use:

### MAR 1 0 2000

Stephen L. Longacre
BioTechnologies For Horticulture, Inc.
100 Independence Mall West
Philadelphia, PA 19196-2399

Subject:

Label Amendment: Decrease in the Content of Active Ingredient (1-Methylcyclopropene) from 0.43% to 0.14%, in the Label and the CSF.

Product EthylBloc®. EPA Registration Number: 71297-1

Your Submission of March 8, 2000

Dear Mr. Longacre

The amendment referred above submitted in connection with the registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended, is acceptable. A copy of the stamped label is enclosed for your records.

Submit five copies of the final printed labeling before you release this product for shipment.

If you have any questions regarding this action, please contact Driss Benmhend at (703) 308-9525.

Sincerely,

Janet L. Andersen, Ph. D., Director Biopesticides and Pollution

Prevention Division (7511C)

brent L. Clades

Enclosures

(Container label first page only; insert label all pages)

### EthylBloc<sup>®</sup>

EthylBloc® is a powder that, when mixed with a Mixing/Buffer solution or water, releases a gas to extend the life and usefulness of many fresh cut flowers, potted flowers, bedding, nursery and foliage plants. Plants are treated with this gas in enclosed areas such as rooms, coolers, greenhouses, truck trailers and shipping boxes/containers. This product is intended for use only on ornamental, non-food crops. Do not use outdoors or in other non-enclosed areas.

Active Ingredient: 1-Methylcyclopropene ...... 0.14%
Other Ingredients: 99.86%
Total: 100.00%

### ACCEPTED MAR 10 2000

Under the Federal lacecticide, Fungicide, and Redemicide Act. on amended, for the posticide registered under EPA Reg. No. 71297-1

### KEEP OUT OF REACH OF CHILDREN CAUTION

### Statement of Practical Treatment

IF IN EYES: Flush with plenty of water. Call a physician if irritation persists. IF ON SKIN: Wash with plenty of soap and water. Get medical attention. IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

Refer to insert label for additional Precautionary Statements and Directions for Use.

Manufactured by: Biotechnologies for Horticulture, Inc.

751 Thunderbolt Road Walterboro, SC 29488

For product information call toll-free (800) 323-3689

EPA Registration No.: 71297-1

EPA Establishment No.: 71297-SC-001

U.S. Patent No. 5,518,988

Net Contents: 1.34 oz. [38 grams (water soluble packet)], 2.6 oz. [75 grams

(water soluble packet)] and 3.5 oz. [100 grams]

EthylBloo® Last label revision March 8, 2000 Page 1 of 9

### PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and mixers of this product must wear:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Protective eyewear (goggles or face shield).
- Rubber gloves.
- As a general precaution when exposed to a gas, for activities in enclosed areas wear a respirator with either an organic vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number-prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G).
- Applicators and handlers must follow manufacturer's instructions for cleaning / maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original packaging in a cool, dry place.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

EthylBloc® can extend the life and usefulness of many fresh cut flowers and potted flowers, bedding, nursery and foliage plants. It works by inhibiting the negative effects of ethylene and thus prevents or reduces premature flower death, leaf and/or flower fall, and leaf yellowing.

EthylBloc is specifically designed to be used by all levels of the floral and nursery industries, including growers, shippers, wholesalers, bouquet

EthylBloc®
Last label revision March 8, 2000
Page 2 of 9

98%

manufacturers, mail-order houses and retailers (such as florists, garden centers, nurseries and mass-market outlets). EthylBloc is very easy to use with almost no labor costs.

EthylBloc® can be used just prior to harvest, immediately after harvest, just prior to shipment, upon arrival from the supplier, and/or just prior to sale. It comes with two scoops for easy measuring and the proper Mixing/Buffer Solution. [Optional: EthylBloc® is in a water soluble package for easy use with the proper Buffer (mixing) solution.] The Mixing/Buffer Solution is used to facilitate gas release. [{text optional} Users can substitute tap water for the Mixing/Buffer Solution but the gas release will not be as efficient. Contact the manufacturer for specific directions.] EthylBloc® is more effective under warm temperature conditions, 55° to 75°F, (13° to 24° C). Longer treatment times are required for plants held under temperatures below 55°F, (13° C).

### Flowers And Plants

EthylBloc® treatment benefits many flowers and plants such as:

Achillea, Aconitum, Agapanthus, Alchemilla, Allium, Alstroemeria, Alyssum, Aphelandra, Aquilegia, Asclepias, Astrantia, Asparagus Fern, Azalea, Begonia, Bouvardia, Brassaia (Schefflera), Brodiaea (Triteleia), Calathea, Campanula, Carnation, Celosia, Centaurea, Chamaedorea, Chelone, Coleus, Cordyline, Cymbidium, Crocosmia (Montbretia), Daucus (Queen Annes Lace), Delphinium, Dendrobium, Dianthus, Dicentra, Dizygotheca, Doronicum, Echium, Eremurus, Eustoma (Lisianthus), Ficus, Freesia, Fuchsia, Geranium, Gladiolus, Godetia, Gypsophila, Hibiscus, Ilex (Holly), Impatiens, Ixia, Kalanchoe, Kniphofia, Lavatera, Lily, Lysimachia, Miniature Carnation, Monkshood, Pelargonium, Petunia, Philodendron, Phlox, Physostegia, Poinsettia, Radermachera, Rose, Rudbeckia, Salvia, Saponaria, Scabiosa, Silene, Snapdragon, Solidaster, Stock, Streptocarpus, Sweet William, Trachelium, Trollius, Veronica, Wax Flower, and Zygocactus.

To realize maximum benefits, plants should be treated whether or not they may have been previously treated with EthylBloc® or another anti-ethylene product. Shipments already treated with EthylBloc® do not have to be retreated, however, retreating is not harmful and can even be beneficial. Some species that would likely benefit from additional applications include those with more than one flower per stem (i.e. snapdragons, delphiniums, miniature carnations and alstroemena) and flowers at different stages of development on the same blant (i.e. geraniums, impatiens, and azaleas).

### TREATMENT INSTRUCTIONS

1. Calculate the treatment volume by measuring the length, width and height of the treatment area in feet or meters. Multiply these three numbers

EthylBloc® Last label revision March 8, 2000 Page 3 of 9 together to obtain the volume of the room/area in cubic feet or cubic meters. For example, if a room is 4 feet wide, 5 feet long and 5 feet high, the volume equals 100 cubic feet.

- 2. Wear all Personal Protective Equipment (PPE) required under Precautionary Statements.
- 3. Use a plastic mixing container large enough to hold the EthylBloc<sup>®</sup> and Mixing/Buffer Solution. A plastic pail works well for larger applications, a plastic bowl or similar container for smaller applications.
- 4. First add Mixing/Buffer Solution to the mixing container. Then add the EthylBloc® powder. The amounts of EthylBloc® and Mixing/Buffer Solution are specified in the following tables/boxes. [or {For Water Soluble Packets} First add Mixing/Buffer Solution to the mixing container. Then add the water soluble packet of EthylBloc® to the mixing container, making sure the water soluble packet is covered. The amounts of EthylBloc® and Mixing/Buffer Solution are specified in the following tables/boxes.]
- Following the addition of EthylBloc® to the Mixing/Buffer Solution, leave the treatment area immediately. Make sure the area is sufficiently sealed. See following application sections for details.
- 6. POSTING: Signs should be posted on all potential entry points during EthylBloc7 treatment (for at least four hours or as otherwise recommended in the Directions for Use). Signs should state "CAUTION. Do not enter area. EthylBloc® treatment underway." Posting is suggested as a means of ensuring optimal effectiveness of EthylBloc®.
- 7. After the treatment period ends (see below tables/boxes for specified treatment periods), ventilate treated areas with outside air before reentry.
- 8. Remaining treatment solution can be disposed of on site or at an approved waste disposal facility.

EthylBloc® Last label revision March 8, 2000 Page 4 of 9

98%

### SPECIFIC TREATMENT PERIODS

TREATMENT	CONDITIO	DNS: 5!	5 – 75 °f	. 4 to	8 hours

TREATMENT RATE: 1.5 gram of EthylBloc plus 1 fl oz Mixing Solution per 100 cubic feet

Amount of EthylBloc	Amount of Mixing Solution	Cubic Feet to Treat
1 White Scoop	1 tsp	13
1 Green Scoop	2 Tbsp	100
38 g Water Soluble Packet	25 fl oz or 3 cups plus 2 Tbsp	2500
75 g Water Soluble Packet	50 fl oz or 6 cups plus 4 Tosp	5000

#### METRIC EQUIVALENT

Amount of EthylBloc	Amount of Mixing Solution	Cubic Meters to Treat
1 White Scoop	5 ml	0.4
1 Green Scoop	30 ml	3
38 g Water Soluble Packet	750 ml	75
75 g Water Soluble Packet	1500 ml	150

### TREATMENT CONDITIONS: 55 to 75 °F, minimum 10 hours

TREATMENT RATE: 1.5 gram of EthylBloc plus 1 fl oz Mixing Solution per 200 cubic feet

Amount of EthylBloc	Amount of Mixing Solution	Cubic Feet to Treat
1 White Scoop	1 tsp	26
1 Green Scoop	2 Tosp	200
38 g Water Soluble Packet	25 fl oz or 3 cups plus 2 Tosp	5000
75 g Water Soluble Packet	50 fl oz or 6 cups plus 4 Tosp	10000

#### METRIC EQUIVALENT

Amount of EthylBloc	Amount of Mixing Solution	Cubic Meters to Treat
1 White Scoop	5 ml	0.8
1 Green Scoop	30 ml	6
38 g Water Soluble Packet	750 ml	150
75 g Water Soluble Packet	1500 ml	300

### TREATMENT CONDITIONS: 35 to 55 °F, minimum 10 hours

TREATMENT RATE: 1.5 gram of EthylBloc plus 1.5 fl oz Mixing Solution per 100 cubic feet

Amount of EthylBloc	Amount of Mixing Solution	Cubic Feet to Trea	rt
1 White Scoop	1.5 tsp	13	
1 Green Scoop	3 Tbsp	100	
38 g Water Soluble Packet	37 ft oz <u>or</u> 4 2/3 cups	2500	
75 g Water Soluble Packet	75 fl oz or 9 1/3 cups	5000	

### METRIC EQUIVALENT

Amount of EthylBloc	Amount of Mixing Solution	Cubic Meters to Treat
1 White Scoop	7 ml	0.4
1 Green Scoop	45 ml	3
38 g Water Soluble Packet	1125 ml	75
75 g Water Soluble Packet	2250 ml	150

EthylBloc® Last label revision March 8, 2000 Page 5 of 9

#### Measurements:

WHITE SCOOP = 0.2 grams EthylBloc® powder GREEN SCOOP = 1.5 grams EthylBloc® powder

1 teaspoon = 1 tsp = 5 ml

1 Tablespoon = 1 Tbsp = 3 tsp = 1/2 fl oz

1 fl oz = 2 Tbsp = 30 ml

1 cup = 8 fl oz = 240 ml

38 gram Water Soluble Packet will treat a 20 ft truck container

75 gram Water Soluble Packet will treat a 40 ft truck container

### APPLICATION IN GREENHOUSES PRIOR TO HARVEST

Fresh cut flowers and bedding, potted flowering, nursery and foliage plants can be treated in the greenhouse just prior to being harvested.

- The greenhouse must be tightly constructed. Plastic covered houses (especially Adouble-poly@) are generally tighter than fiberglass or glass covered ones.
- 2. Sections of greenhouses can be enclosed with plastic to make the treatment area smaller, as long as it is sealed sufficiently to prevent the gas from escaping. Excessive leakage reduces effectiveness of EthylBloc®.
- Make sure all greenhouse vents are closed. Night treatment is recommended mainly because vent closing is more realistic and treatment times can be longer.
- 4. Any internal air circulation system (that does not bring in outside air) should remain on during treatment to help distribute the gas.
- 5. All greenhouse treatments should be done at temperatures greater than 55°F (13° C).
- 6. When calculating treatment volumes, use 2 of the height measured at the ridge/peak for the height measurement. If a greenhouse is 25 feet wide, 100 feet long and 10 feet high, the approximate volume equals 25 x 100 x 10/2 = 12,500 cubic feet.
- 7. Follow steps under Treatment Instructions.

EthylBloc® Last label revision March 8, 2000 Page 6 of 9

98%

### APPLICATION IN ENCLOSED AREAS SUCH AS: HOLDING/STORAGE ROOMS. COOLERS, AND TRUCK TRAILERS

Plants being held in enclosed areas can be easily treated with EthylBloc®. For example, non-boxed sleeved potted plants and cut flowers (held dry or in solution), or boxed plants and cut flowers with the lids and/or precooling vents completely open and directly exposed to the surrounding atmosphere can be treated. Bedding or potted plants on movable racks are also easily treated.

### Typical treatment areas

- Retail and wholesale florist coolers including walk-in, storage and/or walk-in/storage combinations;
- Delivery trucks or vans, truck trailers, inter-modal containers, regardless of their size/volume;
- Any room in a building that can be isolated, sealed and aerated/vented to the outside after treatment.
- 1. Treatment areas should be checked for gas leakage. Excessive leakage reduces effectiveness of EthylBloc®.
- If needed, use plastic liners, tape and/or other products and procedures to make enclosed areas more gas/air tight
- 3. Any internal air circulation system (that does not bring in outside air) should remain on during treatment to help distribute the gas.
- 4 Temperatures should be between 35° and 75° F (13° and 24° C).
- 5. Follow steps under Treatment Instructions.

### APPLICATION IN AREAS SPECIFICALLY BUILT FOR ETHYLBLOG ...

General EthylBloc® Treatment Chamber. It might be appropriate to construct an area to be used solely for EthylBloc® treatment. Constructing such specifies. EthylBloc® treatment areas has proven to be an effective way of using EthylBloc®. This maximizes EthylBloc® effectiveness and reduces costs by requiring less product to treat a given number of plant units.

While this treatment area could be built using a number of gas impermeable materials, 4.0 to 6.0 mil polyethylene sheeting works well. Just make sure the unit seals properly.

EthylBloc® Last label revision March 8, 2000 Page 7 of 9

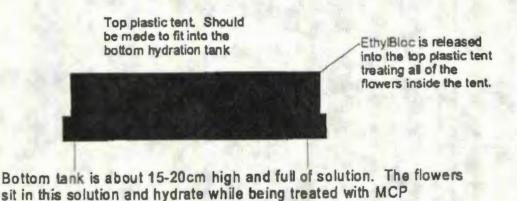
98%

One way to help ensure a good seal where the plastic comes in contact with the flooring is to use hydration solution. The treatment unit base is submerged in a trough of hydration solution a few inches deep thus making a good seal where gas cannot escape.

To use such a treatment area, follow the treatment instructions adjusting for treatment volume and temperatures.

Cut Flower Hydration EthylBloc® Treatment Chamber. The top of the chamber can be made of 4.0 to 6.0 mil polyethylene sheeting and a wooden frame, or a single plastic piece that can fit into the bottom hydration tank, or something similar. The bottom tank can be any size tub that is capable of holding hydration solution and flowers. See drawing below.

Figure 1



[{Optional text for similar text above in box} Bottom tank is about 6 to 8 inches (15-20 cm) high and full of hydration solution. The flowers sit in this solution and hydrate while being treated with EthylBloc®.]

Place the flowers in bunches or in buckets in the bottom tank. Place the too plastic tent over the bottom holding tank. The tent's bottom edges must be able to be submerged into the hydration solution in the bottom holding tank to insure a seal. Follow Treatment Instructions making sure the EthylBiooxi mixture remains separate from the hydration solution throughout the treatment.

EthylBloc® Last label revision March 8, 2000 Page 8 of 9 WARRANTY Biotechnologies for Horticulture Inc. warrants that this material conforms to the chemical description on the label. Biotechnologies for Horticulture Inc. neither makes nor authorizes any agent or representative to make any other warranty of fitness or of merchantability, guarantee or representation, express or implied, concerning this material. The maximum liability for breach of this warranty shall not exceed the purchase price of this product. Biotechnologies for Horticulture Inc.'s maximum liability for breach of this warranty shall not exceed the purchase price of the product. Buyer and user acknowledge and assume all risks and liabilities resulting from the handling, storage and use of this material, whether or not in accordance with directions.

Questions? Contact Biotechnologles for Horticulture toll-free at (800) 538-3320 or call (843) 538-3839

SLL/03Mar00
p:\EthylBloc\Mar00Label.doc

EthylBloc® Last label revision March 8, 2000 Page 9 of 9

98%

PA 19106-2399 U.S.A HMHAAS CENTRAL FAX (215) 592-3377

之 ROHM

March 8, 2000

Mr. Driss Benmhend
Biochemical Pesticides Branch
US EPA Biopesticides and
Pollution Prevention Division (7511C)
Office of Pesticide Programs
1921 Jefferson Davis Highway, CM2
Arlington, VA 22202

SLL-00-074

Dear Mr. Benmhend:

Subject: EthylBloc® (EPA Regis. No. 71297-1)

Active Ingredient = 1-Methylcyclopropene

Revised Label Amendment to Adjust Active Ingredient

Content to 0.14%

Reference: Label Amendment Submitted 03Mar00 (SLL-00-068)

BioTechnologies for Horticulture, Inc. submits the attached revised label amendment to indicate an adjustment in the nominal content of the active ingredient 1-methylcyclopropene (1-MCP) in the registered end-use formulation EthylBloc (EPA Regis. No. 71297-1) to 0.14% from the 0.11% Indicated in our 03Mar00 label amendment submission. Revised Confidential Statements of Formula for both the basic and alternate formulations of EthylBloc reflecting the adjustment to 0.14% 1-MCP in the EthylBloc formulation are also attached.

EthylBloc was registered for use on flowers in April, 1999 by BioTechnologies for Horticulture, Inc. (BTH). Rohm and Haas purchased BTH in December, 1999, and subregistered Floralife Inc. (Walterboro, SC) the use of EthylBloc on flowers at that time.

My 03Mar00 label amendment indicated that we recently discovered that the actual 1-MCP ai content of the EthylBloc end-use formulation was about one-fourth of the 0.43% ai content Indicated on the product label. I indicated that the decreased ai content was not due to any significant change in the manufacturing process, but that it was due to a less rigorous analytical procedure used by Floralife over the past several years. My 03Mar00 label amendment specified the nominal 1-MCP content as 0.11% in EthylBloc end-use product.

We quantify 1-MCP in EthylBloc end-use product by gas chromatography using a flame ionization detector, and using isobutylene as an internal standard. An aliquot of EthylBloc end-use product is dissolved in buffer solution in a sealed vial, and after equilibration, a sample of the headspace gas is analyzed.

Mr. Benmhend 08Mar00 Page 2

The 0.11% ai nominal concentration was determined using an injection port temperature of 250 deg C during the gas chromatographic analysis. Earlier this week, after I had submitted by 03Mar00 label amendment to the Agency, our researchers conducted additional analyses of 1-MCP in EthylBloc using an injection port temperature of 150 deg C in an attempt to reduce a small amount of an apparent degradation product observed in the analysis. Quantitation of 1-MCP in EthylBloc using the reduced injection port temperature of 150 deg C revealed a nominal 1-MCP concentration of 0.14% in the EthylBloc formulation. This slightly greater amount of nominal 1-MCP in the EthylBloc formulation (0.14% vs 0.11%) is likely due to less degradation in the injection port at 150 deg C versus 250 deg C. The only difference in the analyses was the injection port temperature. We now believe 0.14% is the accurate nominal concentration of 1-MCP in the EthylBloc formulation; thus the reason for submitting this revised label amendment.

As I indicated in my 03Mar00 label amendment submission, Floralife, who currently manufactures and sells EthylBloc, stopped production last week when we became aware of this lower ai issue. However, Floralife is a small company and needs to resume production as soon as possible or face significant economic hardship.

Anything that the Agency can do to expedite approval of this revised label amendment so that Floralife may resume production of EthylBloc by the end of this week would be greatly appreciated.

Please contact me by phone (215-592-3581), fax (215-592-3414), or E-mail (rstysl@rohmhaas.com) if you have any questions about this label amendment.

Sincerely.

Stephen L. Longacre, Ph.D.

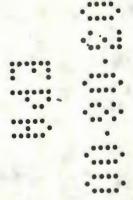
Product Registration Manager Agricultural Chemicals Registration

and Regulatory Affairs Department

Mr. Benmhend 08Mar00 Page 3

Administrative materials submitted with this letter:

- 1) EPA Form 8570-1 (OPP Identifier 267630);
- 2) Revised Product Label for 71297-1 (SLL/08Mar00) (5 copies)
- Revised Confidential Statement of Formula / Basic Formulation (dated 08Mar00); and
- 4) Revised Confidential Statement of Formula / Alternate Formulation (dated 08Mar00).



(WED) 3. 8'00 10:12/ST 10:10/NO. 4260980651 FROM ROHM AND HAAS - AG REG HO **OPP Identifier Number United States** X **Amendment Environmental Protection Agency** 267630 Washington, DC 20460 Other Application for Pesticide - Section I 1. Company/Product Number 2. EPA Product Manager 3. Proposed Classification 71297-1 **Driss Benmhend** 4. Company/Product (Name) PM# Restricted None EthylBloc® 5. Name and Address of Applicant (Include Zip Code) 8. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(l), my product is similar or identical in composition and labeling BioTechnologies for Horticulture, Inc. 100 Independence Mail West EPA Reg. No. \_\_\_\_\_538-256\_ Philadelphia, PA 19106-2399 Product Name: \_\_\_Fertilizer Plus Fungicide XI (Fertilizer + Golden Check if this is a new address Eagle) Section - II Amendment - Explain below. Final printed labels in response to W Agency letter dated "Me Too" Application. Resubmission in response to Agency letter dated Notification - Explain below. Other - Explain below. Explanation: Label amendment to adjust 1-methylcyclopropene active ingredient content on product label from 0.11% to 0.14%, and adjust inert ingredient content on product label from 99.89% to 99.86%, plus revised Confidential Statements of Formula for the basic and an alternate formulation. Section - III 1. Material This Product Will Be Packaged In: Child-Resistant Packaging Water Soluble Packaging Unit Packaging 2. Type of Container Yes" Yes Yes No Plastic No No If "Yes" No. per If Yes' No. per Glass Unit Packaging wgt. container container \* Certification must Package wgt Paper be submitted Other (Specify) 3. Location of Net Contents Information 5. Location of Label Directions 4. Size(s) Retail Container Label Container On Label On Labeling accompanying product 6. Manner in Which Label is Affixed to Product Other Lithograph Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Telephone No. (Include Area Code) Stephen L. Longacre, Ph.D. Product Registration Manager 215 - 592-3581 Date Application
 Received Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. (Stamped)

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

White - EPA File Copy (original)

Yellow - Applicant Copy

Stephen L. Longacre, Ph.D.

2. Signature

Typed Name

**Product Registration Manager** 

3. Title

Date

March 8, 2000

PA 19106-2399 U.S.A.

PUHMHAAS CENTRAL FAX (215) 592-3377



March 8, 2000

Mr. Driss Benmhend
Biochemical Pesticides Branch
US EPA Biopesticides and
Pollution Prevention Division (7511C)
Office of Pesticide Programs
1921 Jefferson Davis Highway, CM2
Arlington, VA 22202

SLL-00-074

Dear Mr. Benmhend:

Subject: EthylBloc® (EPA Regis, No. 71297-1)

Active Ingredient = 1-Methylcyclopropene

Revised Label Amendment to Adjust Active Ingredient

Content to 0.14%

Reference: Label Amendment Submitted 03Mar00 (SLL-00-068)

BioTechnologies for Horticulture, Inc. submits the attached revised label amendment to indicate an adjustment in the nominal content of the active ingredient 1-methylcyclopropene (1-MCP) in the registered end-use formulation EthylBloc (EPA Regis. No. 71297-1) to 0.14% from the 0.11% Indicated in our 03Mar00 label amendment submission. Revised Confidential Statements of Formula for both the basic and alternate formulations of EthylBloc reflecting the adjustment to 0.14% 1-MCP in the EthylBloc formulation are also attached.

EthylBloc was registered for use on flowers in April, 1999 by BioTechnologies for Horticulture, Inc. (BTH). Rohm and Haas purchased BTH in December, 1999, and subregistered Floralife Inc. (Walterboro, SC) the use of EthylBloc on flowers at that time.

My 03Mar00 label amendment indicated that we recently discovered that the actual 1-MCP ai content of the EthylBloc end-use formulation was about one-fourth of the 0.43% ai content Indicated on the product label. I indicated that the decreased ai content was not due to any significant change in the manufacturing process, but that it was due to a less rigorous analytical procedure used by Floralife over the past several years. My 03Mar00 label amendment specified the nominal 1-MCP content as 0.11% in EthylBloc end-use product.

We quantify 1-MCP in EthylBloc end-use product by gas chromatography using a flame ionization detector, and using isobutylene as an internal standard. An aliquot of EthylBloc end-use product is dissolved in buffer solution in a sealed vial, and after equilibration, a sample of the headspace gas is analyzed.

### ATTACHMENTS (2)

Letter from S. L. Longacre, Ph.D. Product Registration Manager, Agricultural Chemicals Registration and Regulatory Affairs Department, Rohm & Haas Co., Philadelphia, PA

to

Driss Benmhend, Regulatory Action Leader, BPPD/BPB

Dated 3/8/2000

### CONCLUSIONS AND RECOMMENDATIONS

BPB supports the label amendment proposed by the registrant for EthylBlood (EPA Reg. no. 71297-1). The description of the analytical methodology, the revised label, and the revised CSFs are acceptable. No additional data are required.

cc: F. Toghrol, R. S. Jones, D. Benmhend, BPPD Subject File R. S. Jones: F.T. CM2, (703) 308-5071: 3/9/2000



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

9 2000

PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Label Amendment for EthylBloc™ (EPA Symbol. No. 071297-1) containing

> 0.14% 1-Methylcyclopropene (Chemical No. 224459), a new active ingredient. Review of Product Chemistry Data, DP Barcode D263880; Case No. 063215;

Submission No. S576467; No MRID No.

Russell S. Jones, Ph.D., Biologist FROM:

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division (7511C)

Freshteh Toghrol, Ph.D., Senior Scientist F. Toghal.

Biochemical Pesticides Property THRU:

Biochemical Pesticides Branch Biopesticides & Pollution Prevention Division (7511C)

TO: Driss Benmhend, Regulatory Action Leader

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division (7511C)

### **ACTION REQUESTED**

Rohm and Haas Co. requests permission to amend the label for EthylBloc™ (EPA Reg. no. 71297-1) to reflect a change in the active ingredient content from 0.43% 1-methylcyclopropene (1-MCP) by weight to 0.14% 1-MCP by weight. The change was requested because new and improved analytical methodology showed that the actual content of 1-MCP in the end-use product was approximately 25% of the a.i. content listed on the label [see attached letter from S. L. Longacre (Rohm and Haas), to D. Benmhend (BPPD), dated 3/8/2000]. In support of the label amendment, the registrant submitted a brief description of the new analytical methodology (see attachment), a revised product label showing a change in the relative amounts of active and other ingredients, and two revised Confidential Statements of Formula (CSFs, dated 3/8/2000) for a basic and alternate formulation.

EthylBloc<sup>TM</sup> is a powdered product that changes to a gas phase (MCP) when mixed with water or a buffering agent. It is intended for non-food use floral and nursery crops.

Mr. Benmhend 08Mar00 Page 2

The 0.11% ai nominal concentration was determined using an injection port temperature of 250 deg C during the gas chromatographic analysis. Earlier this week, after I had submitted by 03Mar00 label amendment to the Agency, our researchers conducted additional analyses of 1-MCP in EthylBloc using an injection port temperature of 150 deg C in an attempt to reduce a small amount of an apparent degradation product observed in the analysis. Quantitation of 1-MCP in EthylBloc using the reduced injection port temperature of 150 deg C revealed a nominal 1-MCP concentration of 0.14% in the EthylBloc formulation. This slightly greater amount of nominal 1-MCP in the EthylBloc formulation (0.14% vs 0.11%) is likely due to less degradation in the injection port at 150 deg C versus 250 deg C. The only difference in the analyses was the injection port temperature. We now believe 0.14% is the accurate nominal concentration of 1-MCP in the EthylBloc formulation; thus the reason for submitting this revised label amendment.

As I indicated in my 03Mar00 label amendment submission, Floralife, who currently manufactures and sells EthylBloc, stopped production last week when we became aware of this lower ai issue. However, Floralife is a small company and needs to resume production as soon as possible or face significant economic hardship.

Anything that the Agency can do to expedite approval of this revised label amendment so that Floralife may resume production of EthylBloc by the end of this week would be greatly appreciated.

Please contact me by phone (215-592-3581), fax (215-592-3414), or E-mail (rstysl@rohmhaas.com) if you have any questions about this label amendment.

Sincerely,

St Longan

Stephen L. Longacre, Ph.D.
Product Registration Manager
Agricultural Chemicals Registration
and Regulatory Affairs Department



# U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7501W) 401 "M" St., S.W. Washington, D.C. 20460

EPA Reg. Number

Date of Issuance:

71297-1

Term of Issuance.

Unconditional

Name of Pesticide Product,

EthylBloc®

NOTICE OF PESTICIDE:

X Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Biotechnologies for Horticulture, Inc. 751 Thunderbolt Road Walterboro, SC 29488

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Blopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Pungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others

This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5) subject to the comments listed below:

- 1. Make the following label changes:
- a. Add the phrase "EPA Registration No. 71297-1 to your label before you release the product for shipment
- b. Add the appropriate Establishment Number to your label before you release the product for shipment
- 2. Submit five copies of the final printed labeling before you release this product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec.6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Unconditional registration does not eliminate the need for continual reassessment of a pesticide. If EPA determines, at any time, that additional data are required to maintain in effect, an existing registration, the Agency will require submission of such data under Section 3(c)(2)(B) of FIFRA.

Signature of the Approving Official

Undusa

4-22 -99

(Container label first page only; insert label all pages)

### **EthylBloc®**

EthylBloc® is a powder that, when mixed with water or a buffer solution, releases a gas to extend the life and usefulness of many fresh cut flowers, potted flowers, bedding, nursery and foliage plants. Crops are treated with this gas in enclosed areas such as rooms, coolers, greenhouses, truck trailers and shipping boxes/containers. This product is intended for use only on ornamental, non-food crops. Do not use outdoors or in other non-enclosed areas.

Active Ingredient: 1-Methylcyclopropene..... 0 .43%
Other Ingredients: 99.57%
Total: 100.00%

### KEEP OUT OF REACH OF CHILDREN CAUTION

### **Statement of Practical Treatment**

IF IN EYES: Flush with plenty of water. Call a physician if irritation persists. IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

Refer to insert label for additional Precautionary Statements and Directions for use.

Manufactured by: Biotechnologies for Horticulture, Inc.

751 Thunderbolt Road Walterboro, SC 29488

For product information call toll-free (800) 323-3689

EPA Registration No.: 71297-1 EPA Establishment No.: 32258-IL-1

U.S. Patent No. 5,518,988

Net Contents: 25, 50, 100 or 200 grams



EthylBloc® Last label revision April 22, 1999 Page 1

### PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and mixers of this product must wear:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Protective eyewear (goggles or face shield).
- Rubber gloves.
- For activities in enclosed areas, wear a respirator with either an organic vaporremoving cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G).
- Applicators and handlers must follow manufacturer's instructions for cleaning / maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

### **USER SAFETY RECOMMENDATIONS**

Users should wash hands thoroughly with soap and water before eating, drinking, chewing gum, using tobacco or using the toilet. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### **DIRECTIONS FOR USE**

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval (REI). The requirements in this box only apply to the uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: long-sleeved shirt, long pants, shoes plus socks, and a respirator with either an organic vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G).

For all applications, notify workers of the application by warning them orally and by posting warning signs outside all entrances to the treated area. Treated areas should be vented with outside air before reentry.

STORAGE AND DISPOSAL Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original packaging in a cool, dry place.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

#### **Directions for Use:**

EthylBloc® is a powder that, when added to a Buffer Solution or water, releases a patented gas (1-Methylcyclopropene, MCP). When used properly, EthylBloc® can extend the life and usefulness of many fresh cut flowers and potted flowers, bedding, nursery and foliage plants. EthylBloc® works by inhibiting the negative effects of ethylene and thus prevents or reduces premature flower death, leaf and/or flower fall, and leaf yellowing.

EthylBloc® is specifically designed to be used by all levels of the floral and nursery industries, including growers, shippers, wholesalers, bouquet manufacturers, mail order houses and retailers (such as florists, garden centers, nurseries and mass market outlets). EthylBloc® is also very easy to use with almost no labor costs.

Some of the many flowers and plants that can benefit from EthylBloc® treatment include:

Achillea, Aconitum, Agapanthus, Alchemilla, Allium, Alstroemeria, Alyssum, Aphelandra, Aquilegia, Asclepias, Astrantia, Asparagus Fern, Azalea, Begonia, Bouvardia, Brassaia (Schefflera), Brodiaea (Triteleia), Calathea, Campanula, Carnation, Celosia, Centaurea, Chamaedorea, Chelone, Coleus, Cordyline, Cymbidium, Crocosmia (Montbretia), Daucus (Queen Annes Lace), Delphinium, Dendrobium, Dianthus, Dicentra, Dizygotheca, Doronicum, Echium, Eremurus, Eustoma (Lisianthus), Ficus, Freesia, Fuchsia, Geranium, Gladiolus, Godetia, Gypsophila, Hibiscus, Ilex (Holly), Impatiens, Ixia, Kalanchoe, Kniphofia, Lavatera, Lily, Lysimachia, Miniature Carnation, Monkshood, Pelargonium, Petunia, Philodendron, Phlox, Physostegia, Poinsettia, Radermachera, Rose, Rudbeckia, Salvia, Saponaria, Scabiosa, Silene, Snapdragon, Solidaster, Stock, Streptocarpus, Sweet William, Trachelium, Trollius, Veronica, Wax Flower, and Zygocactus.

Plants must be exposed to this gas in enclosed areas such as greenhouses, rooms, coolers, shipping boxes or trailers. These enclosed areas should be fairly gas tight as excessive leakage will reduce EthylBloc® effectiveness. This product is not intended for use outdoors or in other non-enclosed areas.

EthylBloc® is more effective when plants are exposed to this gas for at least four hours under warm temperature conditions (55° to 75° F, 13° to 24° C). Higher dosages and longer treatment times are required for plants held under lower temperatures (below 55° F, 13° C).

EthylBloc® can be used just prior to harvest, immediately after harvest, just prior to shipment, upon arrival from the supplier, and/or just prior to sale. To realize maximum benefits, all of the crops listed above should be treated whether or not they may have been previously treated with EthylBloc® or another anti-ethylene product at an earlier point in the distribution chain. Shipments that you know have already been treated with

EthylBloc® do not have to be retreated. However, as noted above, retreating is not harmful and can even be beneficial. Examples of some species that would likely benefit from additional applications include those with more than one flower per stem (i.e. snapdragons, delphiniums, miniature carnations and alstroemeria) and flowers at different stages of development on the same plant (i.e. geraniums, impatiens, and azaleas).

EthylBloc® comes with a scoop for easy measurement along with the proper Buffer (mixing) Solution. The Buffer Solution is used to facilitate MCP gas release from the white powdered carrier. It contains 0.75% potassium hydroxide and 0.75% sodium hydroxide in water. Users can substitute tap water for the Buffer Solution but the release of MCP gas will not be as efficient. Contact the manufacturer for specific directions if water is used instead of Buffer Solution. Refer to the information presented below for selecting the right number of EthylBloc® scoops and Buffer Solution volume for your application.

Posting: Signs should be posted on all points of potential entry into treated areas during treatment with EthylBloc® (for at least four hours or as otherwise recommended in the Directions for Use). Signs should state "CAUTION. Do not enter area. EthylBloc® treatment underway." Posting is suggested as a means of ensuring optimal effectiveness of EthylBloc®.

### **APPLICATION IN GREENHOUSES PRIOR TO HARVEST**

Fresh cut flowers and bedding, and potted flowering, nursery and foliage plants can be treated in the greenhouse just prior to being harvested.

### To treat with EthylBloc®:

- 1. The greenhouse must be tightly constructed. Plastic covered houses (especially "double-poly") are generally tighter than fiberglass or glass covered ones.
- 2. Sections of greenhouses can be enclosed with plastic to make the treatment area smaller as long as it is sealed properly to prevent the gas from escaping.
- 3. Make sure all greenhouse vents are closed. Night treatment is recommended mainly because vent closing is more realistic and treatment times can be longer.
- Any internal air circulation system (that does not bring in outside air) should remain on during treatment to help distribute the gas.
- 5. The amount of EthylBloc® required depends on the volume of the greenhouse, treatment temperature and treatment time.

- 6. To determine the approximate greenhouse volume, multiply the greenhouse width x length x ½ of the height measured at the ridge/peak. For example, if a greenhouse is 25 feet wide x 100 feet long x 10 feet high, the approximate volume equals 25 x 100 x 10/2 = 12,500 cubic feet.
- 7. The above-described calculations can also be performed using meters as dosages are presented both in per cubic foot and per cubic meter.
- 8. All greenhouse treatments should be done at temperatures greater than 55° F (13° C).
- 9. For treatment times from four to eight hours, the correct EthylBloc® dosage is one level scoop per 100 cubic feet or one level scoop per 3.0 cubic meters. **Note:** One level scoop equals about 1.5 grams.
- 10. For treatment times from 12 to 16 hours, the correct EthylBloc® dosage is reduced to one level scoop per 200 cubic feet or one level scoop per 6.0 cubic meters.
- 11. The correct amount of Buffer Solution to use is one ounce (about 30 ml) per level scoop of EthylBloc®.
- 12. The mixing container should be made out of plastic and be large enough to hold the EthylBloc® and Buffer Solution. A plastic pail works well for larger applications while a plastic bowl or similar container for smaller applications.
- 13. Please refer to Tables One, Two and Three for examples of recommended EthylBloc® dosages based on room size, treatment temperature and treatment time.

### 14. To mix:

- a. Wear all Personal Protective Equipment (PPE) required under Precautionary Statements.
- b. First add the proper amount of EthylBloc® to the mixing container.
- c. Then add the proper amount of Buffer Solution, making sure that all of the EthylBloc® powder is covered.
- d. Briefly stir the mixture for about 5 to 10 seconds and then leave the treatment area immediately, making sure the area is properly sealed behind you.
- 15. Remaining mixing solution (which no longer contains MCP) can be disposed of on site or at an approved waste disposal facility.

### APPLICATION IN HOLDING/STORAGE ROOMS, COOLERS, TRUCK TRAILERS AND OTHER ENCLOSED AREAS

Non-boxed crops being held in enclosed areas can be easily treated with EthylBloc®. For example, sleeved potted plants and cut flowers (held dry or in solution) that are not boxed can be treated. Boxed plants and cut flowers with the lids and/or precooling vents completely open can also be treated as long as the box openings are directly exposed to the surrounding atmosphere and thus the EthylBloc® gas. Bedding or potted plants on movable racks are easily treated.

Examples of typical areas that could be used for treating crops with EthylBloc® include:

- Retail florist coolers including walk-in, storage and/or walk-in/storage combinations;
- Wholesale florist coolers:
- Delivery trucks or vans, regardless of their size/volume;
- Truck trailers;
- Inter-modal containers;
- Any room in a building that can be isolated, sealed and aerated/vented to the outside after treatment;
- Boxed crops if the boxes were enclosed in plastic such as being shrink-wrapped.

Note: Some of the treatment area examples presented above may require plastic liners, tape and/or other products and procedures to make them more gas tight.

### To treat with EthylBloc®:

- 1.Measure the size of the room/cooler/trailer (length, width and height) in feet or meters.
- 2. Multiply these three numbers together to obtain the volume of the room in cubic feet or cubic meters.

EthylBloc® Last label revision April 22, 1999 Page 7

- 3. Refer to Tables One and Two for the EthylBloc® rates if the treatment room and products are 55° F (13° C) or higher.
- 4. If the treatment and/or product temperature is below 55° F (13° C), the correct EthylBloc® dosage is three level scoops per 100 cubic feet and three level scoops per 3.0 cubic meters (see **Table Three**).
- 5. The mixing container should be made out of plastic and be large enough to hold the EthylBloc® and Buffer Solution. A plastic pail works well for larger applications while a plastic bowl or similar container for smaller applications.
- 6. Please refer to **Table One**, **Two and Three** for examples of the recommended rates based on treatment temperatures and time.

#### 7. To mix:

- a. Wear all Personal Protective Equipment (PPE) required under Precautionary Statements.
- b. First add the proper amount of EthylBloc® to the mixing container;
- c. Then add the proper amount of Buffer Solution, making sure that all of the EthylBloc® powder is covered;
- d. Briefly stir the mixture for about 5 to 10 seconds and then leave the treatment area immediately, making sure the area is properly sealed behind you.
- 8. Remaining mixing solution (which no longer contains MCP) can be disposed of on site or at an approved waste disposal facility.

### APPLICATION IN AREAS SPECIFICALLY BUILT FOR ETHYLBLOC® TREATMENT

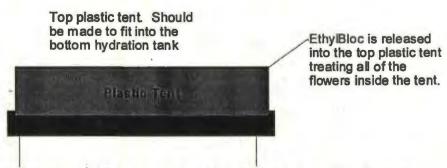
General EthylBloc® Treatment Chamber. It might be appropriate to construct an area to be used solely for EthylBloc® treatment. By doing so one can maximize the EthylBloc® effectiveness and reduce costs by requiring less EthylBloc® to treat a given number of plant units.

While this treatment area could be built using a number of gas impermeable materials, 4.0 to 6.0 mil polyethylene should work well. Just make sure the unit is sealed properly.

One way to help ensure a good seal where the plastic comes in contact with the floor is to use water. Namely, the base (plastic) of the treatment unit is submerged in a trough of water a few inches deep thus making a good seal where gas cannot escape.

To use such a treatment area, follow the same directions presented above for greenhouses and other enclosed areas making sure you adjust the rates based on crop and room temperatures. Constructing such specific EthylBloc® treatment areas has proven to be an effective way of using EthylBloc®.

Cut Flower Hydration EthylBloc® Treatment Chamber. The top of the chamber can be made of 4.0 to 6.0 mil polyethylene and a wooden frame, a single plastic piece that can fit into the bottom hydration tank, or something similar. The bottom tank can be any size tub that is capable of holding solutions. See drawing below.



Bottom tank is about 15-20cm high and full of solution. The flowers sit in this solution and hydrate while being treated with MCP

Place the flowers into the bottom tank in bunches or buckets. Place the top plastic tent over the bottom holding tank. The tent's bottom edges must be able to be submerged into the solution to the bottom of the tank to insure a seal. Lift an end of the tent up and place the bowl or bucket containing EthylBloc® powder into the chamber. Place the Buffer Solution into the bowl or bucket, totally covering the powder. The contents in the bowl/bucket must remain separate from the solution in the tank throughout the treatment. Immediately seal the tent by submerging the walls of the tent in the solution to the bottom of the tank. Follow EthylBloc® use directions already presented.

**Table One:** EthylBloc® and Buffer Solution rates based on treatment temperatures being at least 55° F (13° C) and treatment time be a minimum of four and up to eight hours in various room sizes. Rates not given can be calculated by combining treatment room sizes.

TREATMENT ROOM SIZE		E ETHYLBLOC® Rate: 900ppb		BUFFER SOLUTION		
cubic feet	cubic meters	scoops	Grams	ounces	milliliters	
100	3	1	1.5	1	30	
500	15	5	7.5	5	150	
1000	30	10	15.0	10	300	
2500	75	25	37.5	25	750	
5000	150	50	75.0	50	1500	
10000	300	100	150.0	100	3000	

Note: A minimum four-hour exposure is required. Overnight exposure (eight hours) is even better.

**Table Two**: EthylBloc® and Buffer Solution rates based on treatment temperatures being at least 55° F (13° C) and treatment time be a minimum of 12 to 16 hours in various room sizes. Rates not given can be calculated by combining treatment room sizes.

TREATMENT ROOM SIZE			BLOC® 50 ppb	BUFFER SOLUTION	
cubic feet	cubic meters	scoops	grams	ounces	milliliters
200	6	1	1.5	1	30
1000	30	5	7.5	5	150
2000	60	10	15.0	10	300
5000	150	25	37.5	25	750
10000	300	50	75.0	50	1500
20000	600	100	150.0	100	3000

Note: A minimum 12 to 16-hour exposure is required.

**Table Three:** EthylBloc® and Buffer Solution rates based on treatment temperatures being between 35° and 55° F (3° and 13° C) and treatment time be a minimum of 10 hours in various room sizes. Rates not given can be calculated by combining treatment room sizes.

TREATMENT ROOM SIZE			BUFFER SOLUTION	
cubic meters	scoops	grams	ounces	milliliters
3	1.0	1.5	1.5	45
15	7.5	11.3	7.5	225
30	15.0	22.5	15.0	450
75	30	45	37.5	1125
150	60	90	75.0	2250
300	120	180	150.0	4500
֡֡֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜֜	3 15 30 75 150	Rate: 9           cubic meters         scoops           3         1.0           15         7.5           30         15.0           75         30           150         60	Rate: 900 ppb           cubic meters         scoops         grams           3         1.0         1.5           15         7.5         11.3           30         15.0         22.5           75         30         45           150         60         90	Rate: 900 ppb           cubic meters         scoops         grams         ounces           3         1.0         1.5         1.5           15         7.5         11.3         7.5           30         15.0         22.5         15.0           75         30         45         37.5           150         60         90         75.0

**Note:** a minimum 10 hour exposure period is required for plants and flowers being held at 55° F (13° C) or lower. Longer exposures are even better.

WARRANTY Biotechnologies for Horticulture Inc. warrants that this material conforms to the chemical description on the label. Biotechnologies for Horticulture Inc. neither makes nor authorizes any agent or representative to make any other warranty of fitness or of merchantability, guarantee or representation, express or implied, concerning this material. The maximum liability for breach of this warranty shall not exceed the purchase price of this product. Biotechnologies for Horticulture Inc.'s maximum liability for breach of this warranty shall not exceed the purchase price of the product. Buyer and user acknowledge and assume all risks and liabilities resulting from the handling, storage and use of this material, whether or not in accordance with directions.

Questions? Contact Biotechnologies for Horticulture toll-free at (800) 538-3320 or call (843) 538-3839

c:/ethblc7.doc

APR 20 1999

#### **MEMORANDUM**

SUBJECT: Consideration of unconditional registration of the new chemical

Methylcyclopropene (EPA File Symbol 71297-R; PC Code 224459). This chemical will be used in confined areas to extend the life and usefulness of fresh

cut flowers and potted flowering, bedding nursery and foliage plants

.... DECISION MEMORANDUM .....

FROM: Janet L. Andersen, Director

Biopesticides and Pollution Prevention Division (7511C)

TO: Susan B. Hazen, Acting Deputy Director

Office of Pesticide Programs

#### ISSUE

Should the Agency grant unconditional registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for Methylcyclopropene (MCP) (PC Code 224459)?

This compound will be used in coolers, greenhouses, shipping boxes/containers and other enclosed areas to extend the life and usefulness of fresh cut flowers and potted flowering, bedding nursery and foliage plants.

#### CONCLUSION

All data requirements for granting this registration under FIFRA Section 3(c)(5) have been fulfilled. There is no technical compound. The end use product EthylBloc® containing

0.43% of 1- Methylcyclopropene (MCP), is manufactured by an integrated process. MCP has a nontoxic mode of action, and acts as an ethylene inhibitor.

MCP has been considered in light of the relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). A determination has been made that because of the low toxicity and the limited exposure to this product, no unreasonable adverse effects will result from the use of this compound when label instructions are followed. Furthermore, BPPD has not identified any subchronic, chronic, immune, endocrine, or nondietary exposure issues as they may affect children and the general U.S. population.

The end use product is intended for use in non-food enclosed areas. As a result, direct exposure of non-target organisms is not expected to occur. BPPD believes that MCP use according to label directions, should result in no significant adverse effects to wildlife.

Refer to the Executive Summary in the Registration Eligibility Document for methylcyclopropene for more details.

#### OFFICE DIRECTOR'S CONCURRENCE

The Biopesticides and Pollution Prevention Division recommends that methylcyclopropene be unconditionally registered under Section 3(c)(5) of FIFRA.

Concurrence:	Sun B. By	
Non-Concurrence:	- 1	
Date:	4/22/99	

April 21, 1998

Phone conversation with Jess R. Martineau

Subject:

**EthyBloc** 

EPA Reg. No. 71297-R

I talked with Jess Martineau this after noon and informed him that the application for registration for the product listed above has been reviewed again, and more deficiencies have been found in the application package. Roy Sjoblad sent a letter on Feb. 11, 1998 to Mr. Martineau where he detailed all the deficiencies to correct before this application is given further consideration. I explained to Mr. Martineau that the documents he sent and received by the Agency on march 18, 1998 are not sufficient to correct the deficiencies.

I told Mr. Martineau that the following item have to be included:

1- items 05 and 06 of the letter sent by Roy Sjoblad on February 11, 1998.

2- Eco. Toxicity data are required in forms of studies or waiver requests with an explanation of why the Agency should grant Eco. Tox. Waivers for the registration of the product listed above.

At the end of our conversation, Mr. Martineau agreed to send the documents listed above.

Driss Benmhend

OPP/BPPD/BPB



To: Mike Mendelsohn/DC/USEPA/US@EPA
cc: Driss Benmhend/DC/USEPA/US@EPA, Janet
Andersen/DC/USEPA/US@EPA, Roger
Gardner/DC/USEPA/US@EPA, Russell

Jones/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA

Subject: Re: REVISED VERSION: Question about tolerance exemption

Attorney-Client Advice
Do Not Disclose

Suzanne Krolikowski

Suzanne Krolikowski (202) 564-5632 EPA's Office of General Counsel

Mike Mendelsohn

Mike Mendelsohn 04/20/01 07:21 AM

To: Suzanne Krolikowski/DC/USEPA/US@EPA
cc: Driss Benmhend/DC/USEPA/US@EPA, Janet
Andersen/DC/USEPA/US@EPA, Roger
Gardner/DC/USEPA/US@EPA, Russell
Jones/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA

Subject: Re: REVISED VERSION: Question about tolerance exemption

Suzanne,

Suzanne Krolikowski

Mike



Suzanne Krolikowski 04/19/2001 07:46 PM To: Sheryl Reilly/DC/USEPA/US@EPA

cc: Driss Benmhend/DC/USEPA/US@EPA, Janet Andersen/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Roger Gardner/DC/USEPA/US@EPA, Russell

Jones/DC/USEPA/US@EPA

Subject: Re: REVISED VERSION: Question about tolerance exemption

Attorney-Client Advice Do Not Disclose



Suzanne Krolikowski (202) 564-5632 EPA's Office of General Counsel

#### Sheryl Reilly



**Sheryl Reilly** 04/19/2001 09:40 AM

To: Suzanne Krolikowski/DC/USEPA/US@EPA
cc: Driss Benmhend/DC/USEPA/US@EPA, Janet
Andersen/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA, Roger
Gardner/DC/USEPA/US@EPA, Russell
Jones/DC/USEPA/US@EPA

Subject. Re: REVISED VERSION: Question about tolerance exemption



Thanks, Sheryl

#### **Janet Andersen**

04/18/01 07:08 AM

To: Suzanne Krolikowski/DC/USEPA/US@EPA
cc: Driss Benmhend/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA, Roger
Gardner/DC/USEPA/US@EPA, Russell

Jones/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA

Subject: Re: Question about tolerance exemption

Suzanne Krolikowski



#### Suzanne Krolikowski 04/17/01 06:48 PM

To: Janet Andersen/DC/USEPA/US@EPA cc: Driss Benmhend/DC/USEPA/US@EPA

cc: Driss Benmhend/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Roger Gardner/DC/USEPA/US@EPA, Russell

Jones/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA

Subject: Re: Question about tolerance exemption

Attorney-Client Advice Do Not Disclose

Janet and Sheryl,

#### Janet Andersen

Janet Andersen

04/17/2001 04:58 PM

To: Sheryl Reilly/DC/USEPA/US@EPA

cc: Driss Benmhend/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Roger Gardner/DC/USEPA/US@EPA, Russell Jones/DC/USEPA/US@EPA, Suzanne Krolikowski/DC/USEPA/US@EPA

Subject: Re: Question about tolerance exemption



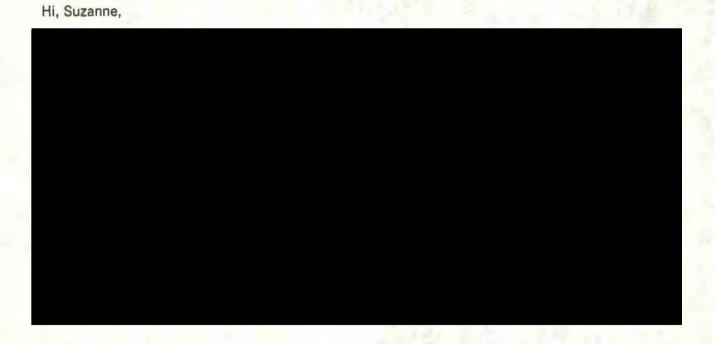


**Sheryl Reilly** 04/17/01 02:30 PM

To: Suzanne Krolikowski/DC/USEPA/US@EPA
cc: Driss Benmhend/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA, Roger
Gardner/DC/USEPA/US@EPA, Russell

Jones/DC/USEPA/US@EPA, (bcc: Janet Andersen/DC/USEPA/US)

Subject: Question about tolerance exemption





Suzanne Krolikowski

04/18/01 05:48 PM

To: Janet Andersen/DC/USEPA/US@EPA
cc: Driss Benmhend/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA, Roger
Gardner/DC/USEPA/US@EPA, Russell

Jones/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA

Subject: REVISED VERSION: Question about tolerance exemption

Attorney-Client Advice Do Not Disclose

Janet and Sheryl,

Janet Andersen

#### Janet Andersen

04/17/2001 04:58 PM

To: Sheryl Reilly/DC/USEPA/US@EPA

cc: Driss Benmhend/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Roger Gardner/DC/USEPA/US@EPA, Russell Jones/DC/USEPA/US@EPA, Suzanne Krolikowski/DC/USEPA/US@EPA

Subject: Re: Question about tolerance exemption



Sheryl Reilly



#### Sheryl Reilly

04/17/01 02:30 PM

To: Suzanne Krolikowski/DC/USEPA/US@EPA
cc: Driss Benmhend/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA, Roger
Gardner/DC/USEPA/US@EPA, Russell

Jones/DC/USEPA/US@EPA, (bcc: Janet Andersen/DC/USEPA/US)

Subject: Question about tolerance exemption



March 10, 2005

Mr. Driss Benmhend Office Of Pesticide Programs (7511C) Biopesticides and Pollution Protection Division U.S Environmental Protection Agency Room 910, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, VA 22202-4501

Dear Mr. Bennihend:

Re: EthylBloc<sup>™</sup> Technology (EPA Registration Number 71297-1) Confidential Statements Of Formula Notification to Add New Sources of Inert Ingredients

Enclosed is an application to notify EPA that additional sources of inert ingredients are being added to the current Confidential Statements of Formula for EthylBloc<sup>TM</sup> Technology (EPA Registration Number 71297-1). Two copies of each of the three revised CSF's for EthylBloc<sup>TM</sup> Technology are enclosed. This amendment is being made by notification and is consistent with the notifications allowed under PR Notice 98-10.

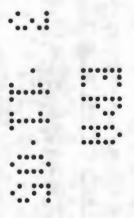
Sincerely

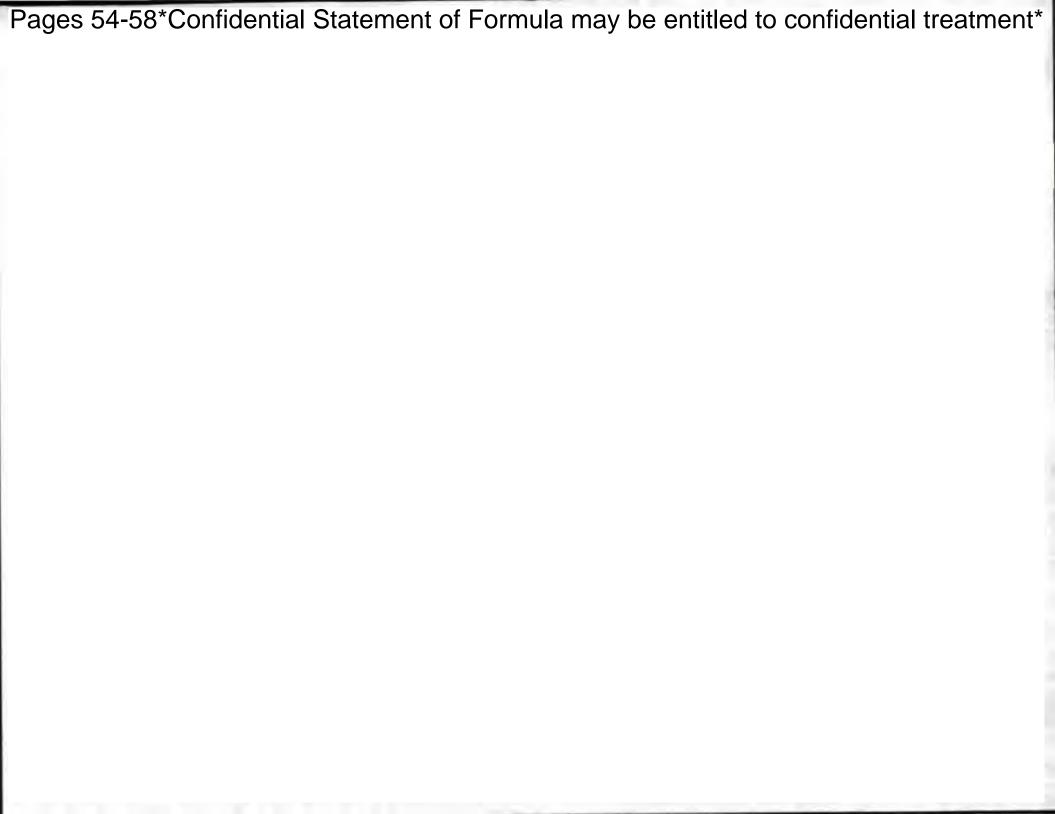
Robert H. Larkin, Ph.D.



Please read instructions on reve	rse before completina form.	Form Apr	proved. OMB No	. 2070-00	060. Approval expires 05-31-98
O FDA	United States Environmental Protection		Registra	ation	OPP Identifier Number
The state of the s	Washington, DC 2046		Other		
-	Application	for Pesticide - Sect			J
1. Company/Product Number		2. EPA Product Mana		3.	Proposed Classification
71297		Driss Benmhend		1	
4. Company/Product (	Name)	PM#			None Destricted
EthylBloc Technology					None Restricted X
5. Name and Address of App	olicant (Include Zip Code)	6. Expedited Review	v. In accordan	ce with	FIFRA Section 3(c)(3)
AgroFresh Inc./Rohm and Haas	Company	(b)(l), my product is s	imilar or identi	cal in co	mposition and labeling
100 Independence Mali West Philadelphia, PA 19106-2399		EPA Reg. No.		NOT	TIFICATION
Timedolphia, Tit 10100 2000		Product Name	Date	Dav.	MONTON
Chapter 1	if this is a new address		D-	HANIE	Wed: 4/20/5
□ <i>Спеск</i>		Section - II	Hevi	ewed	By: FRAZER
Amendment - Explain b			els in response	to	THE CENT
		Agency letter d	ated cation.		
X Notification - Explain be	Now.	Other - Explain			
	page(s) if necessary. (For Secti	on Land Section II \			
or FIFHA and I may be subje	ct to enforcement action and pen	aities under Sections 12 an Section - III	0 14 OT FIFHA.		
1. Material This Product W		Section - III			
Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type o		
Yes*	Yes	Yes		Metal	
No	No	No	1	Plasti	
	If "Yes" No. per	If "Yes" No. per		Glass	
* Certification must	Unit Packaging wgt. container	Package wgt containe	Pr	Pape	
be submitted				Drum	(Specify)
3. Location of Net Contents	Information 4. Size(s	s) Retail Container	5. Location o	f Label	Directions
Label Co	ntainer		On L	abel	
			On L	abeling	accompanying product
6. Manner in Which Label is	Affived to Product	Lithograph	Other		
o. Manner III William Equeris		Paper glued	Olifer		
		Stenciled			
	S	Section - IV			• • • • • • • • • • • • • • • • • • • •
	items directly below for identificati	ion of individual to be conta			
Name Robert H. Larkin	Title President Bed	gulatory Solutions, LLC		one No.	(Include Area Code)
	Certification			6. Da	ate Application
	ive made on this form and all attachm gly false or misleading statement may			Re	oceived
Signature /	n = 1 , 1 3.	Title		1	(Stamped)
Toron	T day b.	ent, Regulatory Solution	ns IIC		
	Fiesiu	ent, regulatory Solution	113, 141		<b>5</b> 0

4. Typed Name	5. Date		
Robert H. Larkin	March 7, 2005	All Company of the	
EPA Form 8570-1 (Rev. 8-94) Previ	ous editions are obsolete.	White - EPA File Copy (original)	Yellow - Applicant Copy







**Mari Duggard** 

09/07/04 01:59 PM

To: rlarkin@agrofresh.com

CC:

Subject: Label changes to EthylBloc (71297-1)

Dear Mr. Larkin,

Per our conversation today (Tuesday 7 Sept 2004), below are the slight revisions that need to be made to the label (Ag Use requirements). Once you have made these changes to the label, please electronically send it via PDF attachment.

revisions in bold: please revise the Ag. Use Requirements statement on page 3 of 11

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. this Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Should you have any questions, comments or concerns please feel free to reply to this e-message, or call me at 703-308-0028.

Sincerely,

Mari L. Duggard,
Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)
703-308-0028

Note to jacket - Courtesy e-mail letting Robert Larkin of AgroFresh, Inc know of TINY deficiencies, as we recently concluded that this product was subject to WPS. (see letter dated 12 Jul 2004)

#### United States Environmental Protection Agency

Robert H. Larkin Agro Fresh Inc. c/o Rohm and Haas Company 100 Independence Mall West Philadelphia, PA 19105 OCT 0 1 2004 766612 | 300

RE: Your Re-submission application dated 6 Aug 2004

Product Name: EthylBloc

EPA Registration Number: 71297-1

Dear Mr. Larkin:

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A), as amended, is acceptable provided that you:

- 1. Submit and/ or cite all data required for registration/ re-registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2. Submit five (5) copies of your final printed labeling before you release the product for your shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass, metal containers, large bags, or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have questions, please contact Mari Duggard, at 703-308-0028, or by e-mail at duggard.mari@epa.gov.

Sincerely,

Sheryl K. Relly, Ph.D., Chief

Biochemical Pesticide Branch

Biopesticides and Pollution

Prevention Division (7511C)

Enc	closures: Co	ny of stamped	Accente FP	YEURRENCES		
SYMBOL >	7511C	7541	75/1C			
SURNAME	Duggard	Peters	Rull			60
~ 7~~	15 Sept 04	9/3/04	91300			00

(Container label first page only; insert label all pages)

## EthylBloc® Technology

EthylBloc® technology is a powder that, when mixed with a Mixing/Buffer solution or water, releases a gas to extend the life and usefulness of many fresh cut flowers, potted flowers, bedding, nursery and foliage plants. Plants are treated with this gas in enclosed areas such as rooms, coolers, greenhouses, truck trailers and shipping boxes/containers. This product is intended for use only on ornamental, non-food crops. Do not use outdoors or in other non-enclosed areas.

Active Ingredient: 1-Methylcyclopropene......0.14%
Other Ingredients: 99.86%
Total: 100.00%

# OCT 0 1 2004 White the Polemal Immediation Programmed and Reduction Particular Teachers and Reduction Particular Teachers and Application Programmed and Series The Particular Regulation Rep. No. 71297-1

## KEEP OUT OF REACH OF CHILDREN CAUTION

#### **FIRST AID**

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. IF SWALLOWED: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For information on this product (including' health concerns, medical emergencies or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378.

Net Contents: 1.34 oz. [38g (water soluble packet], 2.6 oz. [75 g (water soluble packet)], and 3.5 oz. [100 g bottle]

EPA Registration No.: 71297-1

EPA Establishment No.: 32258-SC-001

U.S. Patent No. 5,518,988

EthylBloc® is a registered trademark of Rohm and Haas Company

AgroFresh Inc.

A Fully Owned Subsidiary of Rohm and Haas Company
100 Independence Mall West
Philadelphia, PA 10106
215 592-3000

#### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and mixers of this product must wear:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Protective eyewear (goggles or face shield).
- Rubber gloves.
- As a general precaution when exposed to a gas, for activities in enclosed areas wear a respirator with either an organic vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G).
- Applicators and handlers must follow manufacturer's instructions for cleaning / maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

EthylBloc® Technology Last label revision June 21, 2000 Page 2 of 11

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### **Agricultural Use Requirements**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas prior to venting the volatile active ingredient from the treatment area.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, prior to venting the volatile active ingredient from the treatment area is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks
- Respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G) or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N,R,P, or HE prefilter.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original packaging in a cool, dry place.

Pesticide Disposal: Wastes resulting from the use of this product may be

disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

EthylBloc® can extend the life and usefulness of many fresh cut flowers and potted flowers, bedding, nursery and foliage plants. It works by inhibiting the negative effects of ethylene and thus prevents or reduces premature flower death, leaf and/or flower fall, and leaf yellowing.

EthylBloc<sup>®</sup> is specifically designed to be used by all levels of the floral and nursery industries, including growers, shippers, wholesalers, bouquet manufacturers, mail-order houses and retailers (such as florists, garden centers, nurseries and mass-market outlets). EthylBloc<sup>®</sup> is very easy to use with almost no labor costs.

EthylBloc® can be used just prior to harvest, immediately after harvest, just prior to shipment, upon arrival from the supplier, and/or just prior to sale. It comes with two scoops for easy measuring and the proper Mixing/Buffer Solution. [Optional: EthylBloc® is in a water soluble package for easy use with the proper Buffer (mixing) solution.] The Mixing/Buffer Solution is used to facilitate gas release. [{text optional} Users can substitute tap water for the Mixing/Buffer Solution but the gas release will not be as efficient. Contact the manufacturer for specific directions.] EthylBloc® is more effective under warm temperature conditions, 55° to 75°F, (13° to 24° C). Longer treatment times are required for plants held under temperatures below 55°F, (13° C).

## Flowers And Plants

EthylBloc® treatment benefits many flowers and plants such as:

Achillea, Aconitum, Agapanthus, Alchemilla, Allium, Alstroemeria, Alyssum, Aphelandra, Aquilegia, Asclepias, Astrantia, Asparagus Fern, Azalea, Begonia, Bouvardia, Brassaia (Schefflera), Brodiaea (Triteleia), Calathea, Campanula, Carnation, Celosia, Centaurea, Chamaedorea, Chelone, Coleus, Cordyline, Cymbldium, Crocosmia (Montbretia), Daucus (Queen Annes Lace), Delphinium, Dendrobium, Dianthus, Dicentra, Dizygotheca, Doronicum, Echium, Eremurus, Eustoma (Lisianthus), Ficus, Freesia, Fuchsia, Geranium, Gladiolus, Godetia, Gypsophila, Hibiscus, Ilex (Holly), Impatiens, Ixia, Kalanchoe, Kniphofia, Lavatera, Lily, Lysimachia, Miniature Carnation, Monkshood, Pelargonium, Petunia, Philodendron, Phlox, Physostegia, Poinsettia, Radermachera, Rose, Rudbeckia, Salvia, Saponaria, Scabiosa, Silene, Snapdragon, Solidaster, Stock, Streptocarpus, Sweet William, Trachelium, Trollius, Veronica, Wax Flower, and Zygocactus.

To realize maximum benefits, treat plants whether or not they may have been previously treated with EthylBloc® or another anti-ethylene product. Shipments already treated with EthylBloc® do not have to be retreated, however, retreating is not harmful and can even be beneficial. Some species that would likely benefit from additional applications include those with more than one flower per stem (i.e. snapdragons, delphiniums, miniature carnations and alstroemeria) and flowers at different stages of development on the same plant (i.e. geraniums, impatiens, and azaleas).

#### TREATMENT INSTRUCTIONS

- 1. Calculate the treatment volume by measuring the length, width and height of the treatment area in feet or meters. Multiply these three numbers together to obtain the volume of the room/area in cubic feet or cubic meters. For example, if a room is 4 feet wide, 5 feet long and 5 feet high, the volume equals 100 cubic feet.
- 2. Wear all Personal Protective Equipment (PPE) required under Precautionary Statements.
- 3. Use a plastic mixing container large enough to hold the EthylBloc® and Mixing/Buffer Solution. A plastic pail works well for larger applications, a plastic bowl or similar container for smaller applications.
- 4. First add Mixing/Buffer Solution to the mixing container. Then add the EthylBloc® powder. The amounts of EthylBloc® and Mixing/Buffer Solution are specified in the tables/boxes below. [or {For Water Soluble Packets} First add Mixing/Buffer Solution to the mixing container. Then add the water soluble packet of EthylBloc® to the mixing container, making sure the water soluble packet is covered. The amounts of EthylBloc® and

EthylBloc® Technology Last label revision June 21, 2000 Page 5 of 11 Mixing/Buffer Solution are specified in the tables/boxes below.]

- 5. Following the addition of EthylBloc® to the Mixing/Buffer Solution, leave the treatment area immediately. Make sure the area is sufficiently sealed. See following application sections for details.
- 6. POSTING: Signs should be posted on all potential entry points during EthylBloc® treatment (for at least four hours or as otherwise recommended in the Directions for Use). Signs should state "CAUTION. Do not enter area. EthylBloc® treatment underway." Posting is suggested as a means of ensuring optimal effectiveness of EthylBloc®.
- 7. After the treatment period ends (see below tables/boxes for specified treatment periods), ventilate treated areas with outside air before reentry.
- 8. Remaining treatment solution can be disposed of on site or at an approved waste disposal facility.

#### SPECIFIC TREATMENT PERIODS

TREATMENT CONDITION	ONS: 55 – 75 °F, 4 to 8 hours	
TREATMENT RATE:	1.5 gram of EthylBloc® plus 1 fl oz Mixing S	olution per 100 cubic feet

Amount of EthylBloc	Amount of Mixing Solution	Cubic Fee	t to Treat
1 White Scoop	1 tap	13	
1 Green Scoop	2 Thep	100	Æ
38 g Water Soluble Packet	25 fl oz or 3 cups plus 2 Tbsp	2500	
75 g Water Soluble Packet	50 fl oz or 6 cups plus 4 Tbsp	5000	

#### **METRIC EQUIVALENT**

Amount of EthylBloc	Amount of Mixing Solution	Cubic Meters to Treat
1 White Scoop	5 ml	0.4
1 Green Scoop	30 ml	3
38 g Water Soluble Packet	750 ml	75
75 g Water Soluble Packet	1500 ml	150

TREATMENT CONDITIONS: 55 to 75 °F, minimum 10 hours

TREATMENT RATE: 1.5 gram of EthylBloc® plus 1 fl oz Mixing Solution per 200 cubic feet

Amount of EthylBloc	Amount of Mixing Solution	Cubic Feet to Treat
1 White Scoop	1 tap	23
1 Green Scoop	2 Thep	200
38 g Welstr Soluble Packet	25 fl oz or 3 cups plus 2 Thep	5000
75 g Water Soluble Packet	50 fl oz or 6 cups plus 4 Tbsp	10000

#### **METRIC EQUIVALENT**

Amount of EthylBloc	Amount of Mixing Solution	<b>Cubic Meters to Treat</b>
1 White Scoop	5 ml	0.8
1 Green Scoop	30 ml	6
38 g Water Soluble Packet	750 mi	150
75 g Water Soluble Packet	1500 ml	300

TREATMENT CONDITIONS: 35 to 55 °F, minimum 10 hours

TREATMENT RATE: 1.5 gram of EthylBloc® plus 1.5 fl oz Mixing Solution per 100 cubic feet

Amount of EthylBloc®	Amount of Mixing Solution	Cubic Feet to Treat	
1 White Scoop	1.5 tap	13	
1 Green Scoop	3 Tbsp	100	
38 g Water Soluble Packet	37 fl oz <u>or</u> 4 2/3 cups	2500	
75 g Water Soluble Packet	75 fl oz or 9 1/3 cups	5000	

#### METRIC EQUIVALENT

Amount of EthylBloc	Amount of Mixing Solution	Cubic Meters to Treat		
1 White Scoop	7 ml	0.4		
1 Green Scoop	45 ml	3		
38 g Water Soluble Packet	1125 ml	75		
75 g Water Soluble Packet	2250 ml	150		

EthylBloc® Technology Last label revision June 21, 2000 Page 7 of 11

#### Measurements:

WHITE SCOOP = 0.2 grams EthylBloc® powder
GREEN SCOOP = 1.5 grams EthylBloc® powder
1 teaspoon = 1 tsp = 5 ml
1 Tablespoon = 1 Tbsp = 3 tsp = ½ fl oz
1 fl oz = 2 Tbsp = 30 ml
1 cup = 8 fl oz = 240 ml
38 gram Water Soluble Packet will treat a 20 ft truck container
75 gram Water Soluble Packet will treat a 40 ft truck container

#### APPLICATION IN GREENHOUSES PRIOR TO HARVEST

Fresh cut flowers and bedding, potted flowering, nursery and foliage plants can be treated in the greenhouse just prior to being harvested.

- 1. The greenhouse must be tightly constructed. Plastic covered houses (especially "double-poly") are generally tighter than fiberglass or glass covered ones.
- 2. Sections of greenhouses can be enclosed with plastic to make the treatment area smaller, as long as it is sealed sufficiently to prevent the gas from escaping. Excessive leakage reduces effectiveness of EthylBloc<sup>®</sup>.
- Make sure all greenhouse vents are closed. Night treatment is recommended mainly because vent closing is more realistic and treatment times can be longer.
- 4. Any internal air circulation system (that does not bring in outside air) should remain on during treatment to help distribute the gas.
- 5. All greenhouse treatments should be done at temperatures greater than 55°F (13° C).
- 6. When calculating treatment volumes, use 2 of the height measured at the ridge/peak for the height measurement. If a greenhouse is 25 feet wide, 100 feet long and 10 feet high, the approximate volume equals 25 x 100 x 10/2 = 12,500 cubic feet.
- 7. Follow steps under Treatment Instructions.

## APPLICATION IN ENCLOSED AREAS SUCH AS: HOLDING/STORAGE ROOMS, COOLERS, AND TRUCK TRAILERS

Plants being held in enclosed areas can be easily treated with EthylBloc<sup>®</sup>. For example, non-boxed sleeved potted plants and cut flowers (held dry or in solution), or boxed plants and cut flowers with the lids and/or precooling vents completely open and directly exposed to the surrounding atmosphere can be treated. Bedding or potted plants on movable racks are also easily treated.

#### Typical treatment areas

- Retail and wholesale florist coolers including walk-in, storage and/or walk-in/storage combinations;
- Delivery trucks or vans, truck trailers, inter-modal containers, regardless of their size/volume;
- Any room in a building that can be isolated, sealed and aerated/vented to the outside after treatment.
- 1. Treatment areas should be checked for gas leakage. Excessive leakage reduces effectiveness of EthylBloc<sup>®</sup>.
- 2. If needed, use plastic liners, tape and/or other products and procedures to make enclosed areas more gas/air tight
- 3. Any internal air circulation system (that does not bring in outside air) should remain on during treatment to help distribute the gas.
- 4 Temperatures should be between 35° and 75° F (13° and 24° C).
- 5. Follow steps under Treatment Instructions.

## APPLICATION IN AREAS SPECIFICALLY BUILT FOR ETHYLBLOC TREATMENT

General EthylBloc® Treatment Chamber. It might be appropriate to construct an area to be used solely for EthylBloc® treatment. Constructing such specific EthylBloc® treatment areas has proven to be an effective way of using EthylBloc®. This maximizes EthylBloc® effectiveness and reduces costs by requiring less product to treat a given number of plant units.

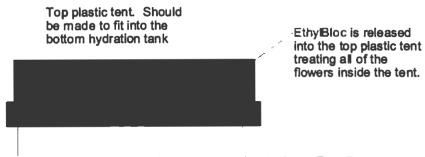
While this treatment area could be built using a number of gas impermeable materials, 4.0 to 6.0 mil polyethylene sheeting works well. Just make sure the unit seals properly.

EthylBloc® Technology Last label revision June 21, 2000 Page 9 of 11 One way to help ensure a good seal where the plastic comes in contact with the flooring is to use hydration solution. The treatment unit base is submerged in a trough of hydration solution a few inches deep thus making a good seal where gas cannot escape.

To use such a treatment area, follow the treatment instructions adjusting for treatment volume and temperatures.

Cut Flower Hydration EthylBloc® Treatment Chamber. The top of the chamber can be made of 4.0 to 6.0 mil polyethylene sheeting and a wooden frame, or a single plastic piece that can fit into the bottom hydration tank, or something similar. The bottom tank can be any size tub that is capable of holding hydration solution and flowers. See drawing below.

Figure 1



Bottom tank is about 15-20cm high and full of solution. The flowers sit in this solution and hydrate while being treated with MCP

[{Optional text for similar text above in box} Bottom tank is about 6 to 8 inches (15-20 cm) high and full of hydration solution. The flowers sit in this solution and hydrate while being treated with EthylBloc®.]

Place the flowers in bunches or in buckets in the bottom tank. Place the top plastic tent over the bottom holding tank. The tent's bottom edges must be able to be submerged into the hydration solution in the bottom holding tank to insure a seal. Follow Treatment Instructions making sure the EthylBloc® mixture remains separate from the hydration solution throughout the treatment.

WARRANTY AgroFresh, Inc, warrants that this material conforms to the chemical description on the label. AgroFresh, Inc, neither makes nor authorizes any agent or representative to make any other warranty of fitness or of merchantability, guarantee or representation, express or implied, concerning this material. The maximum liability for breach of this warranty shall not exceed the purchase price of this product. AgroFresh, Inc's maximum liability for breach of this warranty shall not exceed the purchase price of the product. Buyer and user acknowledge and assume all risks and liabilities resulting from the handling, storage and use of this material, whether or not in accordance with directions.



<b>≎EPA</b>	Environment Wee	hington, DC 20	460	Registr X Amend Other		OPP Identifier Number	
		Application	on for Pesticide - S	ection I			
1. Company/Product Number						Proposed Classification	
71297-1 4. Company/Product (Name)			Driss Benmhend			None Restricted	
EthylBlocTechnology			TOW				
5. Name and Address of Applicant (Include ZIP Code) AgroFresh Inc. 100 Independence Mall West Philadelphia, PA 19106  Check if this is a new address			6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3 (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No.  Product Name				
			Section - II				
Amendment - Explain  Resubmission in resp  Notification - Explain	onee to Agency lette	Agency "Me To	Final printed labels in repsonse to Agency letter deted "Me Too" Application.  Other - Explain below.				
1, Meterial This Product Wil Child-Resistant Peckaging	Ba Packaged in:		Section - III  Water Soluble Packaging	2. Type o	f Container	•	
Yes No	Yes X No		X Yes No		Motel X Plastic Gless		
* Certification must be submitted	if "Yes" Unit Packaging wg	No. per pt. container	If "Yes" No. p Package wgt conta		Paper Other (Spesify)		
3. Location of Net Contents  X Label C	Information		teil Container	5. Location of Le	shal Directio	one .	
6. Manner in Which Label is		× Lithog Paper Stend	raph	ther			
			Section - IV				
1. Contact Point /Complete	items directly below	for identification	on of individual to be contact	red, If necessary, to p	vocass this	application.)	
Name Robert H. Larkin			Trite President, Regulatory Solutions, LL  Telephone No. (Include Area Co				
	ry knowlingily false o		ition all attachments thereto are itement may be punishable to 3. Title  President, Reg	ry fine or imprisorme	nt or • • • •	6. Data Application Resolved, (Stamped)	
b. Typed Name			6. Dote 4.5. August 6, 2004			••••	

#### August 6, 2004

Document Processing Desk (AMEND)
Office Of Pesticide Programs 7504C
U.S. Environmental Protection Agency
Room 266A Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202

Attention: Mari Duggard

Re: EthylBloc<sup>TM</sup> Technology

EPA Registration Number 71297-1

Label Amendment Application To Amend First Aid Statements
Response To Sheryl Reilly Letter dated July 12, 2004

Enclosed are three copies of the draft label for EthylBloc<sup>™</sup> Technology amended as per the recommendations in Dr. Sheryl Reilly's letter of July 12, 2004. The changes to the originally submitted label are highlighted in red. Also enclosed with this resubmission is a completed application form 8570-1. Please let me know if you have any questions or need any additional information for approval of this amended label.

Sincerely

Robert H. Larkin

President

Regulatory Solutions, LLC



(Container label first page only; insert label all pages)

# EthylBloc® Technology

EthylBloc® technology is a powder that, when mixed with a Mixing/Buffer solution or water, releases a gas to extend the life and usefulness of many fresh cut flowers, potted flowers, bedding, nursery and foliage plants. Plants are treated with this gas in enclosed areas such as rooms, coolers, greenhouses, truck trailers and shipping boxes/containers. This product is intended for use only on ornamental, non-food crops. Do not use outdoors or in other non-enclosed areas.

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### **FIRST AID**

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. IF SWALLOWED: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For information on this product (including health concerns, medical emergencies or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378.

Net Contents: 1.34 oz. [38g (water soluble packet], 2.6 oz. [75 g (water soluble packet)], and 3.5 oz. [100 g bottle]

EPA Registration No.: 71297-1

EPA Establishment No.: 32258-SC-001

U.S. Patent No. 5,518,988

EthylBloc® is a registered trademark of Rohm and Haas Company

AgroFresh Inc.

A Fully Owned Subsidiary of Rohm and Haas Company
100 Independence Mall West
Philadelphia, PA 10106
215 592-3000

#### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION.** Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and mixers of this product must wear:

- · Long-sleeved shirt and long pants.
- Shoes plus socks.
- Protective eyewear (goggles or face shield).
- Rubber gloves.
- As a general precaution when exposed to a gas, for activities in enclosed areas wear a respirator with either an organic vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G).
- Applicators and handlers must follow manufacturer's instructions for cleaning / maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

## **Agricultural Use Requirements**

Use this product only in accordance with its labeling and with the Worker Protection
Standard 40 CFR Part 170. This Standard contains requirements for the protection of
agricultural workers on farms, hurseries and greenhouses, and handlers of agricultural
pesticides. It contains requirements for training, decontamination, notification and
emergency assistance. It also contains specific instructions and exceptions pertaining to
the statements on this label about personal protective equipment (PPE) and restricted
entry interval. The requirements in the box only apply to uses of this product that are
covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas prior to venting the volatile active ingredient from the treatment area.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, prior to venting the volatile active ingredient from the treatment area is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks
- Respirator with an organic-vapor removing cartridge with a prefilter approved for
  pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for
  pesticides (MSHA/NIOSH approval number prefix TC-14G) or a NIOSH approved
  respirator with an organic vapor (OV) cartridge or canister with any N,R,P, or HE
  prefilter.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original packaging in a cool, dry place.

Pesticide Disposal: Wastes resulting from the use of this product may be

disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

EthylBloc® can extend the life and usefulness of many fresh cut flowers and potted flowers, bedding, nursery and foliage plants. It works by inhibiting the negative effects of ethylene and thus prevents or reduces premature flower death, leaf and/or flower fall, and leaf yellowing.

EthylBloc® is specifically designed to be used by all levels of the floral and nursery industries, including growers, shippers, wholesalers, bouquet manufacturers, mail-order houses and retailers (such as florists, garden centers, nurseries and mass-market outlets). EthylBloc® is very easy to use with almost no labor costs.

EthylBloc® can be used just prior to harvest, immediately after harvest, just prior to shipment, upon arrival from the supplier, and/or just prior to sale. It comes with two scoops for easy measuring and the proper Mixing/Buffer Solution. [Optional: EthylBloc® is in a water soluble package for easy use with the proper Buffer (mixing) solution.] The Mixing/Buffer Solution is used to facilitate gas release. [{text optional} Users can substitute tap water for the Mixing/Buffer Solution but the gas release will not be as efficient. Contact the manufacturer for specific directions.] EthylBloc® is more effective under warm temperature conditions, 55° to 75°F, (13° to 24° C). Longer treatment times are required for

plants held under temperatures below 55°F, (13°C).

# Flowers And Plants

EthylBloc® treatment benefits many flowers and plants such as:

Achillea, Aconitum, Agapanthus, Alchemilla, Allium, Alstroemeria, Alyssum, Aphelandra, Aquilegia, Asclepias, Astrantia, Asparagus Fern, Azalea, Begonia, Bouvardia, Brassaia (Schefflera), Brodiaea (Triteleia), Calathea, Campanula, Carnation, Celosia, Centaurea, Chamaedorea, Chelone, Coleus, Cordyline, Cymbidium, Crocosmia (Montbretia), Daucus (Queen Annes Lace), Delphinium, Dendrobium, Dianthus, Dicentra, Dizygotheca, Doronicum, Echium, Eremurus, Eustoma (Lisianthus), Ficus, Freesia, Fuchsia, Geranium, Gladiolus, Godetia, Gypsophila, Hibiscus, Ilex (Holly), Impatiens, Ixia, Kalanchoe, Kniphofia, Lavatera, Lily, Lysimachia, Miniature Carnation, Monkshood, Pelargonium, Petunia, Philodendron, Phlox, Physostegia, Poinsettia, Radermachera, Rose, Rudbeckia, Salvia, Saponaria, Scabiosa, Silene, Snapdragon, Solidaster, Stock, Streptocarpus, Sweet William, Trachelium, Trollius, Veronica, Wax Flower, and Zygocactus.

To realize maximum benefits, treat plants whether or not they may have been previously treated with EthylBloc® or another anti-ethylene product. Shipments already treated with EthylBloc® do not have to be retreated, however, retreating is not harmful and can even be beneficial. Some species that would likely benefit from additional applications include those with more than one flower per stem (i.e. snapdragons, delphiniums, miniature carnations and alstroemeria) and flowers at different stages of development on the same plant (i.e. geraniums, impatiens, and azaleas).

#### TREATMENT INSTRUCTIONS

- Calculate the treatment volume by measuring the length, width and height
  of the treatment area in feet or meters. Multiply these three numbers
  together to obtain the volume of the room/area in cubic feet or cubic
  meters. For example, if a room is 4 feet wide, 5 feet long and 5 feet high,
  the volume equals 100 cubic feet.
- 2. Wear all Personal Protective Equipment (PPE) required under Precautionary Statements.
- 3. Use a plastic mixing container large enough to hold the EthylBloc® and Mixing/Buffer Solution. A plastic pail works well for larger applications, a plastic bowl or similar container for smaller applications.
- 4. First add Mixing/Buffer Solution to the mixing container. Then add the

EthylBloc® powder. The amounts of EthylBloc® and Mixing/Buffer Solution are specified in the tables/boxes below. [or {For Water Soluble Packets} First add Mixing/Buffer Solution to the mixing container. Then add the water soluble packet of EthylBloc® to the mixing container, making sure the water soluble packet is covered. The amounts of EthylBloc® and Mixing/Buffer Solution are specified in the tables/boxes below.]

- 5. Following the addition of EthylBloc® to the Mixing/Buffer Solution, leave the treatment area immediately. Make sure the area is sufficiently sealed. See following application sections for details.
- 6. POSTING: Signs should be posted on all potential entry points during EthylBloc® treatment (for at least four hours or as otherwise recommended in the Directions for Use). Signs should state "CAUTION. Do not enter area. EthylBloc® treatment underway." Posting is suggested as a means of ensuring optimal effectiveness of EthylBloc®.
- 7. After the treatment period ends (see below tables/boxes for specified treatment periods), ventilate treated areas with outside air before reentry.
- 8. Remaining treatment solution can be disposed of on site or at an approved waste disposal facility.

# SPECIFIC TREATMENT PERIODS

# TREATMENT CONDITIONS: 55 – 75 °F, 4 to 8 hours TREATMENT RATE: 1.5 gram of EthylBloc® plus 1 fl oz Mixing Solution per 100 cubic feet

Amount of EthylBloc	Amount of Mixing Solution	Cubic Feet to Treat	
1 White Scoop	1 tsp	13	
1 Green Scoop	2 Tbsp	100	
38 g Water Soluble Packet	25 fl oz or 3 cups plus 2 Tbsp	2500	
75 g Water Soluble Packet	50 fl oz or 6 cups plus 4 Tbsp	5000	

#### **METRIC EQUIVALENT**

Amount of EthylBloc	Amount of Mixing Solution	<b>Cubic Meters to Treat</b>
1 White Scoop	5 ml	0.4
1 Green Scoop	30 ml	3
38 g Water Soluble Packet	750 mi	75
75 g Water Soluble Packet	1500 ml	150

### TREATMENT CONDITIONS: 55 to 75 °F, minimum 10 hours

TREATMENT RATE:	1.5 gram of EthylBloc®	plus 1 fl oz Mixing	Solution per 200 cubic feet

Amount of EthylBloc	Amount of Mixing Solution	Cubic Feet to Treat
1 White Scoop	1 tsp	26
1 Green Scoop	2 Tbsp	200
38 g Water Soluble Packet	25 fl oz or 3 cups plus 2 Tbsp	5000
75 g Water Soluble Packet	50 fl oz or 6 cups plus 4 Tbsp	10000

#### METRIC EQUIVALENT

Amount of EthylBloc®	Amount of Mixing Solution	Cubic Meters to Treat
1 White Scoop	5 ml	0.8
1 Green Scoop	30 ml	6
38 g Water Soluble Packet	750 ml	150
75 g Water Soluble Packet	1500 ml	300

# TREATMENT CONDITIONS: 35 to 55 °F, minimum 10 hours

TREATMENT RATE: 1.5 gram of EthylBl	plus 1.5 fl oz Mixing Solution p	per 100 cubic feet
-------------------------------------	----------------------------------	--------------------

Amount of EthylBloc	Amount of Mixing Solution	Cubic Feet to Treat	
1 White Scoop	1.5 tsp	13	
1 Green Scoop	3 Tbsp	100	
38 g Water Soluble Packet	37 fl oz or 4 2/3 cups	2500	
75 g Water Soluble Packet	75 fl oz or 9 1/3 cups	5000	

#### **METRIC EQUIVALENT**

Amount of EthylBloc	Amount of Mixing Solution	Cubic Meters to Treat
1 White Scoop	7 ml	0.4
1 Green Scoop	45 ml	3
38 g Water Soluble Packet	1125 ml	75
75 g Water Soluble Packet	2250 ml	150

#### Measurements:

WHITE SCOOP = 0.2 grams EthylBloc® powder GREEN SCOOP = 1.5 grams EthylBloc® powder

1 teaspoon = 1 tsp = 5 ml

1 Tablespoon = 1 Tbsp = 3 tsp = ½ fl oz

1 fl oz = 2 Tbsp = 30 ml

1 cup = 8 fl oz = 240 ml

38 gram Water Soluble Packet will treat a 20 ft truck container

75 gram Water Soluble Packet will treat a 40 ft truck container

### APPLICATION IN GREENHOUSES PRIOR TO HARVEST

Fresh cut flowers and bedding, potted flowering, nursery and foliage plants can be treated in the greenhouse just prior to being harvested.

- 1. The greenhouse must be tightly constructed. Plastic covered houses (especially "double-poly") are generally tighter than fiberglass or glass covered ones.
- 2. Sections of greenhouses can be enclosed with plastic to make the treatment area smaller, as long as it is sealed sufficiently to prevent the gas from escaping. Excessive leakage reduces effectiveness of EthylBloc®.
- 3. Make sure all greenhouse vents are closed. Night treatment is recommended mainly because vent closing is more realistic and treatment times can be longer.
- 4. Any internal air circulation system (that does not bring in outside air) should remain on during treatment to help distribute the gas.
- 5. All greenhouse treatments should be done at temperatures greater than 55°F (13° C).
- 6. When calculating treatment volumes, use 2 of the height measured at the ridge/peak for the height measurement. If a greenhouse is 25 feet wide, 100 feet long and 10 feet high, the approximate volume equals  $25 \times 100 \times 10/2 = 12,500$  cubic feet.
- 7. Follow steps under Treatment Instructions.

# APPLICATION IN ENCLOSED AREAS SUCH AS: HOLDING/STORAGE ROOMS, COOLERS, AND TRUCK TRAILERS

Plants being held in enclosed areas can be easily treated with EthylBloc®. For example, non-boxed sleeved potted plants and cut flowers (held dry or in solution), or boxed plants and cut flowers with the lids and/or precooling vents completely open and directly exposed to the surrounding atmosphere can be treated. Bedding or potted plants on movable racks are also easily treated.

#### Typical treatment areas

- Retail and wholesale florist coolers including walk-in, storage and/or walk-in/storage combinations;
- Delivery trucks or vans, truck trailers, inter-modal containers, regardless of their size/volume;
- Any room in a building that can be isolated, sealed and aerated/vented to the outside after treatment.
- 1. Treatment areas should be checked for gas leakage. Excessive leakage reduces effectiveness of EthylBloc®.
- 2. If needed, use plastic liners, tape and/or other products and procedures to make enclosed areas more gas/air tight
- 3. Any internal air circulation system (that does not bring in outside air) should remain on during treatment to help distribute the gas.
- 4 Temperatures should be between 35° and 75° F (13° and 24° C).
- 5. Follow steps under Treatment Instructions.

# APPLICATION IN AREAS SPECIFICALLY BUILT FOR ETHYLBLOC TREATMENT

General EthylBloc® Treatment Chamber. It might be appropriate to construct an area to be used solely for EthylBloc® treatment. Constructing such specific EthylBloc® treatment areas has proven to be an effective way of using EthylBloc®. This maximizes EthylBloc® effectiveness and reduces costs by requiring less product to treat a given number of plant units.

While this treatment area could be built using a number of gas impermeable materials, 4.0 to 6.0 mil polyethylene sheeting works well. Just make sure the

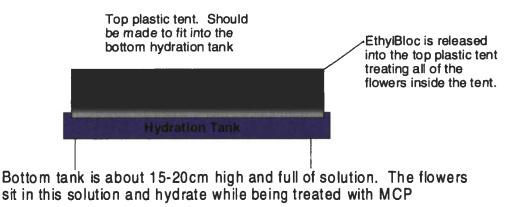
unit seals properly.

One way to help ensure a good seal where the plastic comes in contact with the flooring is to use hydration solution. The treatment unit base is submerged in a trough of hydration solution a few inches deep thus making a good seal where gas cannot escape.

To use such a treatment area, follow the treatment instructions adjusting for treatment volume and temperatures.

Cut Flower Hydration EthylBloc® Treatment Chamber. The top of the chamber can be made of 4.0 to 6.0 mil polyethylene sheeting and a wooden frame, or a single plastic piece that can fit into the bottom hydration tank, or something similar. The bottom tank can be any size tub that is capable of holding hydration solution and flowers. See drawing below.

Figure 1



[{Optional text for similar text above in box} Bottom tank is about 6 to 8 inches (15-20 cm) high and full of hydration solution. The flowers sit in this solution and hydrate while being treated with EthylBloc@.]

Place the flowers in bunches or in buckets in the bottom tank. Place the top plastic tent over the bottom holding tank. The tent's bottom edges must be able to be submerged into the hydration solution in the bottom holding tank to insure a seal. Follow Treatment Instructions making sure the EthylBloc® mixture remains separate from the hydration solution throughout the treatment.

WARRANTY AgroFresh, Inc, warrants that this material conforms to the chemical description on the label. AgroFresh, Inc, neither makes nor authorizes any agent or representative to make any other warranty of fitness or of merchantability, guarantee or representation, express or implied, concerning this material. The maximum liability for breach of this warranty shall not exceed the purchase price of this product. AgroFresh, Inc's maximum liability for breach of this warranty shall not exceed the purchase price of the product. Buyer and user acknowledge and assume all risks and liabilities resulting from the handling, storage and use of this material, whether or not in accordance with directions.

#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

753151 300 n/a 12

Robert H. Larkin Agro Fresh Inc. c/o Rohm and Haas Company 100 Independence Mall West Philadelphia, PA 19105

JUL 1 2 2004

Subject:

Label Amendment Application to update First Aid statement per

PRN 2001-1 dated: 27 Jan 2004

Product Name: Ethylbloc

EPA Registration Number: 71297-1

Dear Mr. Larkin:

The amendment referred to above, submitted in connection with registration under FIFRA-section 3(c)(7)(A), cannot be approved until revisions are made. The changes that need to be made are annotated on the enclosed draft label and described below.

(1) Net Contents/Address:

Please add the Net Contents or Weight of product to the label.

'Please include full company mailing address

See label annotations page 1

(2) First Aid Statements:
Remove "by mouth" in 'If Swallowed' instructions.

Add: "For information on this product (including health concerns, medical emergencies or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378."

See label annotations page 1

(3) Directions for Use:

Please revise this section according to PR Notice 2000-5;

- a. "To realize maximum benefits, treat plants whether or not..."
- b. "The amount of EthylBloc and Mixing/ Buffer Solution are specified in the tables/ boxes below."

See label annotations pages 4 and 5

			CONCURRENC	ES			
SYMBOL	7511c				Administration (manage		
SURNAME	DU66APD						
DATE	8 JUL 04		*************			• • • • • • • • • • • • • • • • • • •	
EPA Form	n 1320-1A (1/90)		Printed on Recycled	l Paper		OFFICIA	AL FEE SPY

### (4) Worker Protection Standard (WPS)

Your product was mistakenly registered without WPS language. After reviewing the label for the amendment, it was determined that your product falls within the scope of the Worker Protection Standard and therefore the label must be revised to contain the appropriate verbiage for WPS. Refer to 40 CFR 170.1, PR Notices 93-7 & -11, and the LRM 3<sup>rd</sup> edition Chapter 10.

We apologize for the oversight and any inconvenience this may cause. Please revise and resubmit your label. If you have questions, please contact Mari Duggard, at 703-308-0028, or by e-mail at <a href="mailto:duggard.mari@epa.gov">duggard.mari@epa.gov</a>.

Sincerely,

Sheryl K. Reilly, Ph.D., Chief Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511C)

Enclosures: Copy of draft label with comments

1093

\* COPPECTIONS + SUGGESTIONS IN BOTH BLACK + CED INK ON COPY.

Draft

# (Container label first page only; Insert label all pages) EthylBloc® Technology

EthylBloc® technology is a powder that, when mixed with a Mixing/Buffer solution or water, releases a gas to extend the life and usefulness of many fresh cut flowers, potted flowers, bedding, nursery and foliage plants. Plants are treated with this gas in enclosed areas such as rooms, coolers, greenhouses, truck trailers and shipping boxes/containers. This product is intended for use only on ornamental non-food crops. Do not use outdoors or in other non-enclosed areas

Active Ingredient: 1-Methylcyclopropene ...... 0.14% Other Ingredients: ...... 99.86% 

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### **FIRST AID**

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. IF SWALLOWED: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

EPA Registration No.: 71297-1

EPA Establishment No.: 32258-SC-001

U.S. Patent No. 5,518,988

AgroFresh Inc. is a fully-owned subsidiary of Rohm and Haas Company

EthylBloc® is a registered trademark of Rohm and Haas Company

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid breathing vapor. thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and mixers of this product must wear:

- Protective eyewear (goggles or face shield).
  Rubber gloves.
  As a general and long pants. As a general precaution when exposed to a gas, for activities in enclosed areas wear a respirator with either an organic vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G).
- Applicators and handlers must follow manufacturer's instructions for cleaning / maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

# DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original packaging in a cool, dry place.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stav out of smoke.

EthylBloc® can extend the life and usefulness of many fresh cut flowers and potted flowers, bedding, nursery and foliage plants. It works by inhibiting the negative effects of ethylene and thus prevents or reduces premature flower death, leaf and/or flower fall, and leaf yellowing.

EthylBloc® is specifically designed to be used by all levels of the floral and

nursery industries, including growers, shippers, wholesalers, bouquet manufacturers, mail-order houses and retailers (such as florists, garden centers, nurseries and mass-market outlets). EthylBloc® is very easy to use with almost no labor costs.

EthylBloc® can be used just prior to harvest, immediately after harvest, just prior to shipment, upon arrival from the supplier, and/or just prior to sale. It comes with two scoops for easy measuring and the proper Mixing/Buffer Solution. [Optional: EthylBloc® is in a water soluble package for easy use with the proper Buffer (mixing) solution.] The Mixing/Buffer Solution is used to facilitate gas release. [{text optional} Users can substitute tap water for the Mixing/Buffer Solution but the gas release will not be as efficient. Contact the manufacturer for specific directions.] EthylBloc® is more effective under warm temperature conditions, 55° to 75°F, (13° to 24° C). Longer treatment times are required for plants held under temperatures below 55°F, (13° C).

# Flowers And Plants

EthylBloc® treatment benefits many flowers and plants such as:

Achillea, Aconitum, Agapanthus, Alchemilla, Allium, Alstroemeria, Alyssum, Aphelandra, Aquilegia, Asclepias, Astrantia, Asparagus Fern, Azalea, Begonia, Bouvardia, Brassaia (Schefflera), Brodiaea (Triteleia), Calathea, Campanula, Carnation, Celosia, Centaurea, Chamaedorea, Chelone, Coleus, Cordyline, Cymbidium, Crocosmia (Montbretia), Daucus (Queen Annes Lace), Delphinium, Dendrobium, Dianthus, Dicentra, Dizygotheca, Doronicum, Echium, Eremurus, Eustoma (Lisianthus), Ficus, Freesia, Fuchsia, Geranium, Gladiolus, Godetia, Gypsophila, Hibiscus, Ilex (Holly), Impatiens, Ixia, Kalanchoe, Kniphofia, Lavatera, Lily, Lysimachia, Miniature Carnation, Monkshood, Pelargonium, Petunia, Philodendron, Phlox, Physostegia, Poinsettia, Radermachera, Rose, Rudbeckia, Salvia, Saponaria, Scabiosa, Silene, Snapdragon, Solidaster, Stock, Streptocarpus, Sweet William, Trachelium, Trollius, Veronica, Wax Flower, and Zygocactus.

To realize maximum benefits, plants should be treated whether or not they may have been previously treated with EthylBloc® or another anti-ethylene product. Shipments already treated with EthylBloc® do not have to be retreated, however, retreating is not harmful and can even be beneficial. Some species that would likely benefit from additional applications include those with more than one flower per stem (i.e. snapdragons, delphiniums, miniature carnations and alstroemeria) and flowers at different stages of development on the same plant (i.e. geraniums, impatiens, and azaleas).

TREATMENT INSTRUCTIONS

- 1. Calculate the treatment volume by measuring the length, width and height of the treatment area in feet or meters. Multiply these three numbers together to obtain the volume of the room/area in cubic feet or cubic meters. For example, if a room is 4 feet wide, 5 feet long and 5 feet high, the volume equals 100 cubic feet.
- 2. Wear all Personal Protective Equipment (PPE) required under Precautionary Statements.
- 3. Use a plastic mixing container large enough to hold the EthylBloc® and Mixing/Buffer Solution. A plastic pail works well for larger applications, a plastic bowl or similar container for smaller applications.
- 4. First add Mixing/Buffer Solution to the mixing container. Then add the EthylBloc® powder. The amounts of EthylBloc® and Mixing/Buffer Solution are specified in the Vallewing tables/boxes. [or {For Water Soluble Packets} First add Mixing/Buffer Solution to the mixing container. Then add the water soluble packet of EthylBloc® to the mixing container, making sure the water soluble packet is covered. The amounts of EthylBloc® and Mixing/Buffer Solution are specified in the following tables/boxes. [section ]
- 5. Following the addition of EthylBloc® to the Mixing/Buffer Solution, leave the treatment area immediately. Make sure the area is sufficiently sealed. See following application sections for details.
- 6. POSTING: Signs should be posted on all potential entry points during EthylBloc® treatment (for at least four hours or as otherwise recommended in the Directions for Use). Signs should state "CAUTION. Do not enter area. EthylBloc® treatment underway." Posting is suggested as a means of ensuring optimal effectiveness of EthylBloc®.
- 7. After the treatment period ends (see below tables/boxes for specified treatment periods), ventilate treated areas with outside air before reentry.
- 8. Remaining treatment solution can be disposed of on site or at an approved waste disposal facility.

# SPECIFIC TREATMENT PERIODS

# TREATMENT CONDITIONS: 55 – 75 °F, 4 to 8 hours TREATMENT RATE: 1.5 gram of EthylBloc® plus 1 fl oz Mixing Solution per 100 cubic feet

Amount of EthylBloc	Amount of Mixing Solution	Cubic Feet to Treat	
1 White Scoop	1 tap	13	
1 Green Scoop	2 Tbsp	100	
38 g Water Soluble Packet	25 fl oz or 3 cups plus 2 Tbsp	2500	
75 g Water Soluble Packet	50 fl oz or 6 cups plus 4 Tbsp	5000	

#### **METRIC EQUIVALENT**

Amount of EthylBloc	Amount of Mixing Solution	<b>Cubic Meters to Treat</b>
1 White Scoop	5 ml	0.4
1 Green Scoop	30 ml	3
38 g Water Soluble Packet	750 ml	75
75 g Water Soluble Packet	1500 ml	150

### TREATMENT CONDITIONS: 55 to 75 °F, minimum 10 hours

TREATMENT RATE: 1.5 gram of EthylBloc® plus 1 fl oz Mixing Solution per 200 cubic feet

Amount of EthylBloc	Amount of Mixing Solution	Cubic Feet to Treat
1 White Scoop	1 tsp	26
1 Green Scoop	2 Tosp	200
38 g Water Soluble Packet	25 fl oz or 3 cups plus 2 Tosp	5000
75 g Water Soluble Packet	50 fl oz or 6 cups plus 4 Tosp	10000

#### **METRIC EQUIVALENT**

Amount of EthylBloc	Amount of Mixing Solution	Cubic Meters to Treat		
1 White Scoop	5 ml	0.8		
1 Green Scoop	30 ml	6		
38 g Water Soluble Packet	750 ml	150		
75 g Water Soluble Packet	1500 ml	300		

#### TREATMENT CONDITIONS: 35 to 55 °F, minimum 10 hours

TREATMENT RATE: 1.5 gram of EthylBloc® plus 1.5 fl oz Mixing Solution per 100 cubic feet

Amount of EthylBloc	Amount of Mixing Solution	Cubic Feet to Treat
1 White Scoop	1.5 tsp	13
1 Green Scoop	3 Tbsp	100
38 g Water Soluble Packet	37 fl oz or 4 2/3 cups	2500
75 g Water Soluble Packet	75 fl oz or 9 1/3 cups	5000

#### METRIC EQUIVALENT

Amount of EthylBloc	Amount of Mixing Solution	Cubic Meters to Treat		
1 White Scoop	7 ml	0.4		
1 Green Scoop	45 ml	3		
38 g Water Soluble Packet	1125 ml	75		
75 g Water Soluble Packet	2250 ml	150		

#### Measurements:

WHITE SCOOP = 0.2 grams EthylBloc powder GREEN SCOOP = 1.5 grams EthylBloc powder

1 teaspoon = 1 tsp = 5 ml

1 Tablespoon = 1 Tbsp = 3 tsp = ½ fl oz

1 fl oz = 2 Tbsp = 30 ml

1 cup = 8 fl oz = 240 ml

38 gram Water Soluble Packet will treat a 20 ft truck container

75 gram Water Soluble Packet will treat a 40 ft truck container

# APPLICATION IN GREENHOUSES PRIOR TO HARVEST

Fresh cut flowers and bedding, potted flowering, nursery and foliage plants can be treated in the greenhouse just prior to being harvested.

- 1. The greenhouse must be tightly constructed. Plastic covered houses (especially "double-poly") are generally tighter than fiberglass or glass covered ones.
- 2. Sections of greenhouses can be enclosed with plastic to make the treatment area smaller, as long as it is sealed sufficiently to prevent the gas from escaping. Excessive leakage reduces effectiveness of EthylBloc®.
- 3. Make sure all greenhouse vents are closed. Night treatment is recommended mainly because vent closing is more realistic and treatment times can be longer.
- 4. Any internal air circulation system (that does not bring in outside air) should remain on during treatment to help distribute the gas.
- 5. All greenhouse treatments should be done at temperatures greater than 55°F (13° C).
- 6. When calculating treatment volumes, use 2 of the height measured at the ridge/peak for the height measurement. If a greenhouse is 25 feet wide, 100 feet long and 10 feet high, the approximate volume equals  $25 \times 100 \times 10/2 = 12,500$  cubic feet.
- 7. Follow steps under Treatment Instructions.

# APPLICATION IN ENCLOSED AREAS SUCH AS: HOLDING/STORAGE ROOMS, COOLERS, AND TRUCK TRAILERS

Plants being held in enclosed areas can be easily treated with EthylBloc®. For example, non-boxed sleeved potted plants and cut flowers (held dry or in solution), or boxed plants and cut flowers with the lids and/or precooling vents completely open and directly exposed to the surrounding atmosphere can be treated. Bedding or potted plants on movable racks are also easily treated.

### Typical treatment areas

- Retail and wholesale florist coolers including walk-in, storage and/or walk-in/storage combinations;
- Delivery trucks or vans, truck trailers, inter-modal containers, regardless of their size/volume;
- Any room in a building that can be isolated, sealed and aerated/vented to the outside after treatment.
- 1. Treatment areas should be checked for gas leakage. Excessive leakage reduces effectiveness of EthylBloc®.
- 2. If needed, use plastic liners, tape and/or other products and procedures to make enclosed areas more gas/air tight
- 3. Any internal air circulation system (that does not bring in outside air) should remain on during treatment to help distribute the gas.
- 4 Temperatures should be between 35° and 75° F (13° and 24° C).
- 5. Follow steps under Treatment Instructions.

# APPLICATION IN AREAS SPECIFICALLY BUILT FOR ETHYLBLOC TREATMENT

General EthylBloc® Treatment Chamber. It might be appropriate to construct an area to be used solely for EthylBloc® treatment. Constructing such specific EthylBloc® treatment areas has proven to be an effective way of using EthylBloc®. This maximizes EthylBloc® effectiveness and reduces costs by requiring less product to treat a given number of plant units.

While this treatment area could be built using a number of gas impermeable materials, 4.0 to 6.0 mil polyethylene sheeting works well. Just make sure the

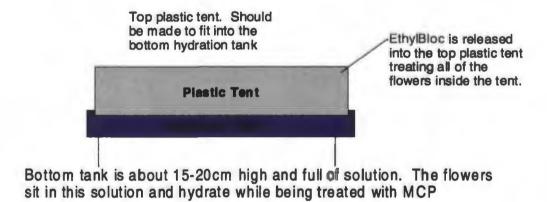
EthylBioc® Technology Last label revision June 21, 2000 Page 8 of 10 unit seals properly.

One way to help ensure a good seal where the plastic comes in contact with the flooring is to use hydration solution. The treatment unit base is submerged in a trough of hydration solution a few inches deep thus making a good seal where gas cannot escape.

To use such a treatment area, follow the treatment instructions adjusting for treatment volume and temperatures.

Cut Flower Hydration EthylBloc® Treatment Chamber. The top of the chamber can be made of 4.0 to 6.0 mil polyethylene sheeting and a wooden frame, or a single plastic piece that can fit into the bottom hydration tank, or something similar. The bottom tank can be any size tub that is capable of holding hydration solution and flowers. See drawing below.

Figure 1



[{Optional text for similar text above in box} Bottom tank is about 6 to 8 inches (15-20 cm) high and full of hydration solution. The flowers sit in this solution and hydrate while being treated with EthylBloc@.]

Place the flowers in bunches or in buckets in the bottom tank. Place the top plastic tent over the bottom holding tank. The tent's bottom edges must be able to be submerged into the hydration solution in the bottom holding tank to insure a seal. Follow Treatment Instructions making sure the EthylBloc® mixture remains separate from the hydration solution throughout the treatment.

WARRANTY AgroFresh, Inc, warrants that this material conforms to the chemical description on the label. AgroFresh, Inc, neither makes nor authorizes any agent or representative to make any other warranty of fitness or of merchantability, guarantee or representation, express or implied, concerning this material. The maximum liability for breach of this warranty shall not exceed the purchase price of this product. AgroFresh, Inc's maximum liability for breach of this warranty shall not exceed the purchase price of the product. Buyer and user acknowledge and assume all risks and liabilities resulting from the handling, storage and use of this material, whether or not in accordance with directions.

(Container label first page only; insert label all pages)

# EthylBloc® Technology

EthylBloc® technology is a powder that, when mixed with a Mixing/Buffer solution or water, releases a gas to extend the life and usefulness of many fresh cut flowers, potted flowers, bedding, nursery and foliage plants. Plants are treated with this gas in enclosed areas such as rooms, coolers, greenhouses, truck trailers and shipping boxes/containers. This product is intended for use only on ornamental, non-food crops. Do not use outdoors or in other non-enclosed areas.

Active Ingredient: 1-Methylcyclopropene...... 0.14%
Other Ingredients: 99.86%
Total: 100.00%

# KEEP OUT OF REACH OF CHILDREN CAUTION

#### **FIRST AID**

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

if IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. IF SWALLOWED: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

EPA Registration No.: 71297-1

EPA Establishment No.: 32258-SC-001

U.S. Patent No. 5,518,988

AgroFresh Inc. is a fully-owned subsidiary of Rohm and Haas Company

EthylBloc® is a registered trademark of Rohm and Haas Company

#### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and mixers of this product must wear:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Protective eyewear (goggles or face shield).
- Rubber gloves.
- As a general precaution when exposed to a gas, for activities in enclosed areas wear a respirator with either an organic vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G).
- Applicators and handlers must follow manufacturer's instructions for cleaning / maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

# **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original packaging in a cool, dry place.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

EthylBloc® can extend the life and usefulness of many fresh cut flowers and potted flowers, bedding, nursery and foliage plants. It works by inhibiting the negative effects of ethylene and thus prevents or reduces premature flower death, leaf and/or flower fall, and leaf yellowing.

EthylBloc® is specifically designed to be used by all levels of the floral and

nursery industries, including growers, shippers, wholesalers, bouquet manufacturers, mail-order houses and retailers (such as florists, garden centers, nurseries and mass-market outlets). EthylBloc<sup>®</sup> is very easy to use with almost no labor costs.

EthylBloc® can be used just prior to harvest, immediately after harvest, just prior to shipment, upon arrival from the supplier, and/or just prior to sale. It comes with two scoops for easy measuring and the proper Mixing/Buffer Solution. [Optional: EthylBloc® is in a water soluble package for easy use with the proper Buffer (mixing) solution.] The Mixing/Buffer Solution is used to facilitate gas release. [{text optional} Users can substitute tap water for the Mixing/Buffer Solution but the gas release will not be as efficient. Contact the manufacturer for specific directions.] EthylBloc® is more effective under warm temperature conditions, 55° to 75°F, (13° to 24° C). Longer treatment times are required for plants held under temperatures below 55°F, (13° C).

# Flowers And Plants

EthylBloc® treatment benefits many flowers and plants such as:

Achillea, Aconitum, Agapanthus, Alchemilla, Allium, Alstroemeria, Alyssum, Aphelandra, Aquilegia, Asclepias, Astrantia, Asparagus Fern, Azalea, Begonia, Bouvardia, Brassaia (Schefflera), Brodiaea (Triteleia), Calathea, Campanula, Carnation, Celosia, Centaurea, Chamaedorea, Chelone, Coleus, Cordyline, Cymbidium, Crocosmia (Montbretia), Daucus (Queen Annes Lace), Delphinium, Dendrobium, Dianthus, Dicentra, Dizygotheca, Doronicum, Echium, Eremurus, Eustoma (Lisianthus), Ficus, Freesia, Fuchsia, Geranium, Gladiolus, Godetia, Gypsophila, Hibiscus, Ilex (Holly), Impatiens, Ixia, Kalanchoe, Kniphofia, Lavatera, Lily, Lysimachia, Miniature Carnation, Monkshood, Pelargonium, Petunia, Philodendron, Phlox, Physostegia, Poinsettia, Radermachera, Rose, Rudbeckia, Salvia, Saponaria, Scabiosa, Silene, Snapdragon, Solidaster, Stock, Streptocarpus, Sweet William, Trachelium, Trollius, Veronica, Wax Flower, and Zygocactus.

To realize maximum benefits, plants should be treated whether or not they may have been previously treated with EthylBloc® or another anti-ethylene product. Shipments already treated with EthylBloc® do not have to be retreated, however, retreating is not harmful and can even be beneficial. Some species that would likely benefit from additional applications include those with more than one flower per stem (i.e. snapdragons, delphiniums, miniature carnations and alstroemeria) and flowers at different stages of development on the same plant (i.e. geraniums, impatiens, and azaleas).

TREATMENT INSTRUCTIONS

- 1. Calculate the treatment volume by measuring the length, width and height of the treatment area in feet or meters. Multiply these three numbers together to obtain the volume of the room/area in cubic feet or cubic meters. For example, if a room is 4 feet wide, 5 feet long and 5 feet high, the volume equals 100 cubic feet.
- 2. Wear all Personal Protective Equipment (PPE) required under Precautionary Statements.
- 3. Use a plastic mixing container large enough to hold the EthylBloc® and Mixing/Buffer Solution. A plastic pail works well for larger applications, a plastic bowl or similar container for smaller applications.
- 4. First add Mixing/Buffer Solution to the mixing container. Then add the EthylBloc® powder. The amounts of EthylBloc® and Mixing/Buffer Solution are specified in the following tables/boxes. [or {For Water Soluble Packets} First add Mixing/Buffer Solution to the mixing container. Then add the water soluble packet of EthylBloc® to the mixing container, making sure the water soluble packet is covered. The amounts of EthylBloc® and Mixing/Buffer Solution are specified in the following tables/boxes.]
- 5. Following the addition of EthylBloc® to the Mixing/Buffer Solution, leave the treatment area immediately. Make sure the area is sufficiently sealed. See following application sections for details.
- 6. POSTING: Signs should be posted on all potential entry points during EthylBloc® treatment (for at least four hours or as otherwise recommended in the Directions for Use). Signs should state "CAUTION. Do not enter area. EthylBloc® treatment underway." Posting is suggested as a means of ensuring optimal effectiveness of EthylBloc®.
- 7. After the treatment period ends (see below tables/boxes for specified treatment periods), ventilate treated areas with outside air before reentry.
- 8. Remaining treatment solution can be disposed of on site or at an approved waste disposal facility.

# SPECIFIC TREATMENT PERIODS

#### TREATMENT CONDITIONS: 55 - 75 °F, 4 to 8 hours

TREATMENT RATE: 1.5 gram of EthylBloc® plus 1 fl oz Mixing Solution per 100 cubic feet

Amount of EthylBloc	Amount of Mixing Solution	Cubic Feet to Treat	
1 White Scoop	1 tsp	13	
1 Green Scoop	2 Tbsp	100	
38 g Water Soluble Packet	25 fl oz or 3 cups plus 2 Tbsp	2500	
75 g Water Soluble Packet	50 fl oz or 6 cups plus 4 Tbsp	5000	

#### METRIC EQUIVALENT

Amount of EthylBloc®	Amount of Mixing Solution	<b>Cubic Meters to Treat</b>
1 White Scoop	5 ml	0.4
1 Green Scoop	30 ml	3
38 g Water Soluble Packet	750 ml	75
75 g Water Soluble Packet	1500 ml	150

#### TREATMENT CONDITIONS: 55 to 75 °F, minimum 10 hours

TREATMENT RATE: 1.5 gram of EthylBloc® plus 1 fl oz Mixing Solution per 200 cubic feet

Amount of EthylBloc	Amount of Mixing Solution	Cubic Feet to Treat		
1 White Scoop	1 tsp	26		
1 Green Scoop	2 Tbsp	200		
38 g Water Soluble Packet	25 fl oz or 3 cups plus 2 Tbsp	5000		
75 g Water Soluble Packet	50 fl oz or 6 cups plus 4 Tbsp	10000		

#### **METRIC EQUIVALENT**

Amount of EthylBloc	Amount of Mixing Solution	Cubic Meters to Treat		
1 White Scoop	5 ml	0.8		
1 Green Scoop	30 ml	6		
38 g Water Soluble Packet	750 ml	150		
75 g Water Soluble Packet	1500 ml	300		

#### TREATMENT CONDITIONS: 35 to 55 °F, minimum 10 hours

TREATMENT RATE: 1.5 gram of EthylBloc® plus 1.5 fl oz Mixing Solution per 100 cubic feet

Amount of EthylBloc	Amount of Mixing Solution	Cubic Feet to Treat
1 White Scoop	1.5 tep	13
1 Green Scoop	3 Tbsp	100
38 g Water Soluble Packet	37 fl oz or 4 2/3 cups	2500
75 g Water Soluble Packet	75 fl oz or 9 1/3 cups	5000

#### METRIC EQUIVALENT

Amount of EthylBloc	Amount of Mixing Solution	Cubic Meters to Treat	
1 White Scoop	7 ml	0.4	
1 Green Scoop	45 ml	3	
38 g Water Soluble Packet	1125 ml	<b>7</b> 5	
75 g Water Soluble Packet	2250 ml	150	

#### Measurements:

WHITE SCOOP = 0.2 grams EthylBloc® powder GREEN SCOOP = 1.5 grams EthylBloc® powder

1 teaspoon = 1 tsp = 5 ml

1 Tablespoon = 1 Tbsp = 3 tsp = ½ fl oz

1 fl oz = 2 Tbsp = 30 ml

1 cup = 8 fl oz = 240 ml

38 gram Water Soluble Packet will treat a 20 ft truck container

75 gram Water Soluble Packet will treat a 40 ft truck container

# APPLICATION IN GREENHOUSES PRIOR TO HARVEST

Fresh cut flowers and bedding, potted flowering, nursery and foliage plants can be treated in the greenhouse just prior to being harvested.

- 1. The greenhouse must be tightly constructed. Plastic covered houses (especially "double-poly") are generally tighter than fiberglass or glass covered ones.
- 2. Sections of greenhouses can be enclosed with plastic to make the treatment area smaller, as long as it is sealed sufficiently to prevent the gas from escaping. Excessive leakage reduces effectiveness of EthylBloc®.
- 3. Make sure all greenhouse vents are closed. Night treatment is recommended mainly because vent closing is more realistic and treatment times can be longer.
- 4. Any internal air circulation system (that does not bring in outside air) should remain on during treatment to help distribute the gas.
- 5. All greenhouse treatments should be done at temperatures greater than 55°F (13° C).
- 6. When calculating treatment volumes, use 2 of the height measured at the ridge/peak for the height measurement. If a greenhouse is 25 feet wide, 100 feet long and 10 feet high, the approximate volume equals  $25 \times 100 \times 10/2 = 12,500$  cubic feet.
- 7. Follow steps under Treatment Instructions.

# APPLICATION IN ENCLOSED AREAS SUCH AS: HOLDING/STORAGE ROOMS, COOLERS, AND TRUCK TRAILERS

Plants being held in enclosed areas can be easily treated with EthylBloc<sup>®</sup>. For example, non-boxed sleeved potted plants and cut flowers (held dry or in solution), or boxed plants and cut flowers with the lids and/or precooling vents completely open and directly exposed to the surrounding atmosphere can be treated. Bedding or potted plants on movable racks are also easily treated.

### Typical treatment areas

- Retail and wholesale florist coolers including walk-in, storage and/or walk-in/storage combinations;
- Delivery trucks or vans, truck trailers, inter-modal containers, regardless of their size/volume;
- Any room in a building that can be isolated, sealed and aerated/vented to the outside after treatment.
- 1. Treatment areas should be checked for gas leakage. Excessive leakage reduces effectiveness of EthylBloc®.
- 2. If needed, use plastic liners, tape and/or other products and procedures to make enclosed areas more gas/air tight
- 3. Any internal air circulation system (that does not bring in outside air) should remain on during treatment to help distribute the gas.
- 4 Temperatures should be between 35° and 75° F (13° and 24° C).
- 5. Follow steps under Treatment Instructions.

# APPLICATION IN AREAS SPECIFICALLY BUILT FOR ETHYLBLOC TREATMENT

General EthylBloc® Treatment Chamber. It might be appropriate to construct an area to be used solely for EthylBloc® treatment. Constructing such specific EthylBloc® treatment areas has proven to be an effective way of using EthylBloc®. This maximizes EthylBloc® effectiveness and reduces costs by requiring less product to treat a given number of plant units.

While this treatment area could be built using a number of gas impermeable materials, 4.0 to 6.0 mil polyethylene sheeting works well. Just make sure the

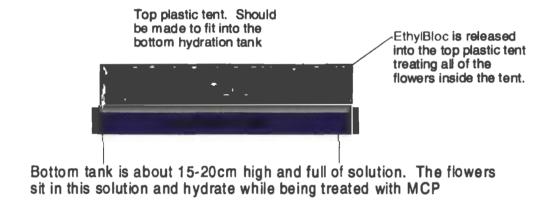
unit seals properly.

One way to help ensure a good seal where the plastic comes in contact with the flooring is to use hydration solution. The treatment unit base is submerged in a trough of hydration solution a few inches deep thus making a good seal where gas cannot escape.

To use such a treatment area, follow the treatment instructions adjusting for treatment volume and temperatures.

Cut Flower Hydration EthylBloc® Treatment Chamber. The top of the chamber can be made of 4.0 to 6.0 mil polyethylene sheeting and a wooden frame, or a single plastic piece that can fit into the bottom hydration tank, or something similar. The bottom tank can be any size tub that is capable of holding hydration solution and flowers. See drawing below.

Figure 1



[{Optional text for similar text above in box} Bottom tank is about 6 to 8 inches (15-20 cm) high and full of hydration solution. The flowers sit in this solution and hydrate while being treated with EthylBloc®.]

Place the flowers in bunches or in buckets in the bottom tank. Place the top plastic tent over the bottom holding tank. The tent's bottom edges must be able to be submerged into the hydration solution in the bottom holding tank to insure a seal. Follow Treatment Instructions making sure the EthylBloc® mixture remains separate from the hydration solution throughout the treatment.

WARRANTY AgroFresh, Inc., warrants that this material conforms to the chemical description on the label. AgroFresh, Inc, neither makes nor authorizes any agent or representative to make any other warranty of fitness or of merchantability, guarantee or representation, express or implied, concerning this material. The maximum liability for breach of this warranty shall not exceed the purchase price of this product. AgroFresh, Inc's maximum liability for breach of this warranty shall not exceed the purchase price of the product. Buyer and user acknowledge and assume all risks and liabilities resulting from the handling, storage and use of this material, whether or not in accordance with directions.



### January 27, 2004

Office Of Pesticide Programs (7511C)
Biocides and Pollution Prevention Division
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attention: Mr. Driss Benmhend

Dear Mr. Benmhend:

Re: EthylBloc™ Technology EPA Registration No. 71297-1 Active Ingredient = 1-Methylcyclopropene PR Notice 2001-1

PR Notice 2001-1 requires registrants to amend the First Aid Statements on their pesticide product labels and contains recommended label language. Enclosed are five copies of the label for EthylBloc™ Technology which has been modified according to the recommendations in PR Notice 2001-1. The changes on the label are highlighted in red.

Please let me know if you have any questions or need any further information.

Sincerely,

Kolmul // Xarcke.

Robert H. Larkin

<b>\$EPA</b>	Environmenta	United States I Protecti lington, DC 20	on Agency	1	Registre Amend Other		OPP Identifier Number
		Applicati	on for Pesticide - Sc	ection			
1. Company/Product Number 71297		2. EPA Product Manager 3 Driss Benmhend		3. P	roposed Classification  None Restricted		
4. Company/Product (Name EthylBloc Technology			PM#			V	
5. Name and Address of A AgroFresh Inc./Rohr 100 Independence N Philadelphia, PA 19	m and Haas Com Mall West			ct is sin			h FIFRA Section 3(c)(3) omposition and labeling
			Section - II				
Amendment - Explain Resubmission in resubmission - Explain - Explain Resubmission - Explain - E	pones to Agency lette	r dated	Agency "Me Too	nted labe letter da o" Applio Explain b	ation.	e to	
Material This Product W Child-Resistant Packaging     Yes	ill Be Packaged In: Unit Packaging Yee		Section - III  Water Soluble Packaging Yes		2. Type of	Containe	r
No	No		No			Plastic	
Certification must submitted	If "Yes" Unit Peckaging wgt	No. per container	If "Yes" No. p Peckage wgt conta			Glass Paper Other	(Specify)
3. Location of Net Contents	Information	4. Size(s) Re	teil Container	5. Lo	ocation of La	bel Direct	ions
6. Manner in Which Label is	Container  s Affixed to Product	Litho	graph O	ther			
T WING! III WING!! Labor!			:HBQ	4			
The state of the s		Otolia	Section - IV				
	e items directly helow		Section - IV	ed if nec	seesary to n	mcass thi	e application l
	e items directly below		Section - IV on of individual to be contacted Title President, Regulatory Sol			Telepho	s application.) ne Nd. (filbluda Area Code) -73\$7
1. Contact Point (Complet) Name Robert H. Larkin I certify that the state	aments I have made of	for identificati  Certification this form and	Title President, Regulatory Sol	utions, L	LC	Telephor 215-641	ne Nd. (fhôlude Area Code)
1. Contact Point (Complet) Neme Robert H. Larkin I certify that the stat I acknowledge that a both under applicable	aments I have made of	for identificati  Certification this form and	Title President, Regulatory Sol	utions, L true, acc y fine or	LC	Telephor 215-641 mplete,	6. Date Application

DP BARCODE: D283049

CASE: 063215 DATA PACKAGE RECORD DATE: 05/15/02

SUBMISSION: S615722 BEAN SHEET Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 320 AMD-LBL REV-DAT REQ H/E R

CHEMICALS: 224459 Cyclopropene, 1-methyl- (7CI, 8CI, 9CI) (CA INDEX NAM 0.1400%

ID#: 071297-00001 ETHYLBLOC COMPANY: 071297 AGRO FRESH INC.

PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL

PM TEAM REVIEWER: DRISS BENMHEND 703-308-9525 ROOM: CS1 5TH FL

RECEIVED DATE: 01/08/02 DUE OUT DATE: 07/07/02

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 283049 EXPEDITE: Y DATE SENT: 05/15/02 DATE RET.: / / HEMICAL: 224459 Cyclopropene,1-methyl- (7CI,8CI,9CI) (CA INDEX NAME)

DP TYPE: 001

CSF: N LABEL: N
ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 10/02/02

REVR: // //
CONTR: // //

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Attached, you will find the following study submitted in support of the tolerance exemption for i-Methylcyclopropene: \* Inhalation Developmental Tox. Study in Rats MRID # 454586-08.

NEGOT DATE:

PROJ DATE:

Please expediate this review Thanks

Driss

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

DP BARCODE: D283051

SUBMISSION: S615723 CASE: 063215 DATA PACKAGE RECORD DATE: 05/15/02

BEAN SHEET Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 320 AMD-LBL REV-DAT REQ H/E R

CHEMICALS: 224459 Cyclopropene, 1-methyl- (7CI, 8CI, 9CI) (CA INDEX NAM 0.1400%

ID#: 071297-00001 ETHYLBLOC COMPANY: 071297 AGRO FRESH INC.

PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL

703-308-9525 ROOM: CS1 PM TEAM REVIEWER: DRISS BENMHEND 5TH FL

RECEIVED DATE: 01/08/02 DUE OUT DATE: 07/07/02

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 283051 EXPEDITE: N DATE SENT: 05/15/02 DATE RET.: HEMICAL: 224459 Cyclopropene,1-methyl- (7CI,8CI,9CI) (CA INDEX NAME)

DP TYPE: 001

CSF: N LABEL: N

DATE ADMIN DUE DATE: 10/02/02 IN DATE OUT ASSIGNED TO NEGOT DATE: DIV : BPPD / / BRAN: BPPD-IO PROJ DATE: SECT: IO REVR : CONTR:

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Attached, you will find the following studies submitted in support of the registration of EthylBloc containing the ai. 1-Methylcyclopropene:

- 1- Product Chemistry MRID# 454586-01
- 2. Analytical Method MRID# 454586-02
- 3. Physical Cem.Charact. MRID# 454586-03
- 4. Acute Dermal Tox. MRID# 454586-04
- 5. Skin Irritation MRID# 454586-05
- 6. Eye Irritation MRID# 454586-06
- 7. Dermal Sensitization MRID# 454586-07

Please review and comment Thanks Driss

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL To: DRISS BENMHEND

U.S. EPA

FAX: 703-308-7026

AGROFRESH/ROHM AND HAAS SUBMISSION OF JUNE 28, 2001

FROM: G

RE:

GEORGE A. HAZELTON, Ph.D.

SENIOR TOXICCLOGIST

ROHM AND HAAS COMPANY

FESEARCH LABORATORIES
727 NORRISTOWN ROAD, PO BOX SD4
SPRING HOUSE PENNSYLVANIA 18477-0804
12151 641-7473 FAX: 12161 610-1821
E-MAR.: RSTOGH@ROHMHAAS.COM



#PAGES = 3

7 profes (including cour page)

bule 1

# Exposures Expressed on a mg/kg/day Basis for Inhalation Studies

Developmental Toxicity Study (Rohm and Haas Report No. 00R-181; MRID 45458608)

SPECIES, SEX	PPM AI	MG AL/L*	MG/KG/DAY**
Rat, females (pregnant)	107 ± 11	0.236	56
	329 ± 25	0.727	174
	1029 ± 53	2.27	543

\* Conversion: mg/L = ppm x 54 (molecular weight of 1-MCP)
24.45 x 1000

\*\* Conversion: 300 g rat inhales 0 2 L/minute for 360 minutes, and an absorption factor of 100% (factor of 1.0).

 $mg/kg/day = mg a.i./L. \times 0.2 l/min \times 360 min.$ 0.3 kg rat

brock 5

TEL:215 619 1618

## Exposures Expressed on a mg/kg/day Basis for Inhalation Studies (continued)

Three Month Inhalation Toxicity Study (Rohm and Haas Report No. 00R-183; MRID 45609001)

SPECIES, SEX	PPM AI	MG AVL	MG AI/KG/DAY
Rat, males	24 ± 5.0		9
	107 ± 7.4		39
	1031 ± 41.1		380
Rat, females	24 ± 5.0		15
	107 ± 7.4		66
	1031 ± 41.1		640

\* conversion: mg/L = ppm x 54 (molecular weight of 1-MCP)
24.45 x 1000

\*\* Conversion: 440 g male rat (or 260 g female rat) inhales 0.2 L/minute for 360 minutes and an absorption factor of 100% (factor of 1.0).

 $mg/kg/day = mg a.i./L \times 0.2 l/min \times 360 min.$ 0.44 kg male rat (or 0.26 kg female rat)

bush 3

MAY. -15' 02 (WED) 13:03

## Consumer Risk Based on Number of Apples Consumed

## Assumptions:

Residues in apple: 4.0 ppb or 4.0 ug/kg [overall average found in apples, see residue data].

Apple size: 200 g or 0.2 kg apple

Weight of individual: 60 kg adult or 10 kg child

### Toxicology endpoints:

Acute exposure (single day) = 56 mg/kg/day [This is NOEL from developmental toxicity study and there was no evidence of developmental toxicity].

Chronic exposure (lifetime) = 9 mg/kg/day [This is NOEL from subchronic study].

### Adult apple consumption:

Amount of residue adult could eat based on acute NOEL

Single day exposure:  $56 \text{ mg/kg/day} \times 60 \text{ kg} = 3360 \text{ mg} \text{ or } 3,360,000 \text{ ug}$ This is the amount that could be consumed by an adult on any single day.

An apple weighing 0.2 kg that contains 4 ug/kg reside (or 4 ppb) will have 0.8 ug of residue in each apple.

Amount of apples could be consumed in a single day by adult = 3,360,000 ug ÷ 0.8 ug per apple = 4,200,000 apples

Conclusion: an adult would need to consume 4,200,000 apples on a single day.

Amount of residue adult could cat based on subchronic NOEL

Multiple day exposure:  $9 \text{ mg/kg/day} \times 60 \text{ kg} = 540 \text{ mg} \text{ or } 540,000 \text{ ug}$ This is the amount that could be consumed by an adult every day of his/her life.

An apple weighing 0.2 kg that contains 4 ug /kg reside (or 4 ppb) will have 0.8 ug of residue in each apple.

Amount of apples could be consumed in a multiple days by adult = 540,000 ug ÷ 0.8 ug per apple = 675,000 apples

Conclusion: an adult would need to consume 675,000 apples every day of his/her life.

page 4

## Child apple consumption:

Amount of residue child could eat based on acute NOEL

Single day exposure:  $56 \text{ mg/kg/day} \times 10 \text{ kg} = 560 \text{ mg} \text{ or } 560,000 \text{ ug}$  This is the amount that could be consumed by a child on any single day.

An apple weighing 0.2 kg that contains 4 ug /kg reside (or 4 ppb) will have 0.8 ug of residue in each apple.

Amount of apples could be consumed in a single day by child = 560,000 ug ÷ 0.8 ug per apple = 700,000 apples

Conclusion: a child would need to consume 700,000 apples on a single day.

Amount of residue child could eat based on subchronic NOEL

Single day exposure:  $9 \text{ mg/kg/day } \times 10 \text{ kg} = 90 \text{ mg or } 90,000 \text{ ug}$ This is the amount that could be consumed by a child every day.

An apple weighing 0.2 kg that contains 4 ug /kg reside (or 4 ppb) will have 0.8 ug of residue in each apple.

Amount of apples could be consumed in every day by child = 90,000 ug ÷ 0.8 ug per apple = 112,500 apples

Conclusion: a child would need to consume 112,500 apples every day.

page 5

97%

## Projected Residues in Other Fruits and Vegetables

In apples the overall average residues was 3 to 4 ppb (see table below). A theoretical maximum for apples would be approx. 9 ppb. In risk calculations previously submitted to agency we used worst case value of 10 ppb.

#### Residue Data:

## Summary of Residues of 1-MCP in Different Apple Varsities

[All values are adjusted for maximum use rate of 1000 ppm a.i. (v/v)]\*

Apple Variety	Average residue ppb	Min. Residue	Max. Residue	Number of Samples
Red Delicious	2.8	1.0	5.0	21
Gala	4.3	1.9	7.6	15
Granny Smith	3.3	1.5	6.1	12
Fuji	2.7	1.2	4.0	12
Overall	3.3	1.0	7.6	60

<sup>\*</sup>Residue studies were conducted using an application rate of 1200 ppm 1-MCP (v/v); however, the maximum use rate on the label will only be 1000 ppm 1-MCP (v/v). Residue values were adjusted using the following factor- 0.833 (or 1000/1200)<sup>18</sup>.

Estimates of residues in other representive crops can be calculated by knowing treatment rates, packing density of fruit (or vegetable) and assuming worst case-all 1-MCP goes into fruit or vegetable (see calculations next page).

page 6

96%

## Estimate of Risk to Consumer (Dietary Exposure)

10 ppb is a worst-case default for each food commodity, since the theoretical maximum residue concentration is 9 ppb or less.

## Example (for apples):

Max. Residue Conc. = max. use rate (mg a.i./m<sup>3</sup> + packing density (kg/M<sup>3</sup>)

Assumes all 1-MCP released ends up in apples.

Apples: 2.24 mg a.i./ $M^3 + 250 \text{ kg/}M^3 = 0.0089 \text{ mg } 1\text{-MCP/kg apples}$  (or 9 ppb)

Theoretical maximum residue concentration for each commodity:

Maximum use rate (ppb)	Maximum use rate (mg a.i./M³)	Packing density (kg/M³)	Maximum Residue (ppb)
1000	2.24	250	9.0
500	1.12	250	4.5
300	0.67	145	4.6
1000	2.24	257	8.7
1000	2.24	250	9.0
	1000 500 300 1000	rate (ppb)     rate (mg a.i√M³)       1000     2.24       500     1.12       300     0.67       1000     2.24	rate (ppb)         rate (mg a.i./M³)         (kg/M³)           1000         2.24         250           500         1.12         250           300         0.67         145           1000         2.24         257

Conclusion: Using packing density of commodity and treatment rates it can be shown with representative commodities that the theoretical maximum would be no more than 9.0 ppb (or no more than 10 ppb).

press 7

96%

CABLE ADDRESS: ROHMHAAS CENTRAL FAX (215) 592-3000

REPLY TO: RESEARCH LABORATORIES 727 NORRISTOWN ROAD, P.O. BOX 904 SPRING HOUSE, PA 18477-0904 (215) 841-7000 FAX (215) 641-7857



January 2, 2002

Document Processing Desk (APPL)
Office Of Pesticide Programs (7504C)
U. S. Environmental Protection Agency
Mr. Driss Benmhend
Biopesticides and Pollution Prevention Division
Room 266A, Crystal Mall 2
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Mr. Benmhend:

Subject:

Pending application 71297-E, SmartFresh

Your letter of September 21, 2001

In your letter of September 21, 2001 three studies were identified as deficient with respect to the requirements of PR Notice 86-5. A copy of your letter and analysis are enclosed. The deficient studies are identified in your letter as REJ(01), REJ(02) and REJ(03).

These three studies should not have been submitted to you as stand alone studies. They were submitted in error. They are already included as appendices in MRID No. 45458601 as Appendices III, IV, and V. I apologize for the inconvenience which this has caused. Please destroy the studies designated as REJ (01), REJ (02), and REJ(03) and continue with the review process for application 71297-E. If you have any questions, I can be reached at 215-641-7397. Thank you.

Sincerely,

Robert H. Larkin, Ph.D.

Regulatory Director AgroFresh Inc.

c/o Rohm and Haas Company

4100 INDEPENDENCE MALL WEST, PHILADELPHIA, PA 19106-2399 USA TELEPHONE (215) 592-3000 CABLE ADDRESS: ROHMHAAS CENTRAL FAX (215) 592-3377

REPLY TO: RESEARCH LABORATORIES 727 NORRISTOWN ROAD, P.O. BOX 904 SPRING HOUSE, PA 19477-0804 (215) 641-7000 FAX (215) 641-7857



October 9, 2001

Document Processing Desk (APPL)
Office Of Pesticide Programs (7504C)
U. S. Environmental Protection Agency
Mr. Driss Benmhend
Biopesticides and Pollution Prevention Division
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Dear Mr. Benmhend:

Subject:

Pending application 71297-E, SmartFresh

Your letter of September 21, 2001

In your letter of September 21, 2001 three studies were identified as deficient with respect to the requirements of PR Notice 86-5. A copy of your letter and analysis are enclosed. The deficient studies are identified in your letter as REJ(01), REJ(02) and REJ(03).

These three studies should not have been submitted to you as stand alone studies. They were submitted in error. They are already included as appendices in MRID No. 45458601 as Appendices III, IV, and V. I apologize for the inconvenience which this has caused. Please destroy the studies designated as REJ (01), REJ (02), and REJ(03) and continue with the review process for application 71297-E. If you have any questions, I can be reached at 215-641-7397. Thank you.

Sincerely

Robert H. Larkin, Ph.D.

Regulatory Director

AgroFresh Inc.

c/o Rohm and Haas Company

Driss, put as we will be not be have be washington Both and week Both and were Both and week Both an

June 28, 2001

454586-00



RHL-01-100

Document Processing Desk (APPL)
Office of Pesticide Programs (7504C)
U. S. Environmental Protection Agency
Mr. Driss Benmhend
Biopesticides and Pollution Prevention Division
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Dear Mr. Benmhend:

Subjects: AgroFresh™ Technology (EPA Regis. No. 71297-) E

Active Ingredient = 1-Methylcycloprepene

Application for Section 3 Registration for Indoor Use on Post-Harvested

Fruits and Vegetables

AgroFresh, Inc., a fully-owned subsidiary of Rohm and Haas Company, submits an application for a Section 3 registration for the product SmartPresh , a powdered formulation containing 3.3% 1-methylcyclopropere (1-MCP) active ingredient in

EPA as a plant growth regulator structurally similar to eth lene and other nan cally occurring plant materials, and eligible for a reduced data set requirement. 1-MCP is regulated by the Biopesticides and Pollution Prevention Division (BPPD) of EPA. This new formulation of 1-MCP will be marketed in disposable, ready to use generators. The applicator will place the appropriate generator in the room containing the commodity to be treated and seal off the room during one treatment period.

EthylBloc<sup>®</sup>, a formulation containing 0.14% 1 MCP in was registered for non-food use on flowers and related materials in April, 1999 (EPA Regis. No. 71297-1).

AgroFresh, Inc. (formerly BioTechnologies for Horticulture, Inc.) submitted a petition for an exemption from the requirement of tolerances for 1-MCP residues on food commodities (PP 06144) in April, 2000 in support of a label amendment for indoor use of EthylBloc technology (0.14% 1-MCP) on post-harvest fruits and vegetables. The Notice of Filing was published in the Federal Register in June, 2000. Additional studies, including a preliminary <sup>14</sup>C-1-MCP apple residue study, mutagenicity studies and a two-week rat inhalation study conducted with 1-MCP gas, and a dietary and worker risk assessment document, were submitted to the Agency on 06Apr01 in support of our 1-MCP exemption from tolerance petition (S. Longacre to D. Benmhend; SLL-01-084). Studies presently at the Agency demonstrate that negligible residues (< 0.009 ppm) on apples will result from the indoor post-harvest use of 1-MCP, that 1-MCP is not mutagenic or acutely toxic, and that large margins of safety exist for 1-MCP for both consumers and workers. We believe that sufficient data have been submitted to the Agency to support the granting of the exemption from the requirement of tolerances for 1-MCP residues on food commodities.



Mr. Benmhend 28June01 Page 2

The maximum 1-MCP treatment concentration will be 1 ppm v/v, whether the 1-MCP is released from the 0.14% (EthylBloc) or 3.3% formulation (SmartFresh).

• The Signal Word for SmartFresh will be CAUTION based on the acute toxicity studies submitted previously and with this petition. A proposed label for the commercial indoor use of SmartFresh on post-harvest fruits and vegetables is included in this application. Product chemistry studies on SmartFresh are also submitted in this application.

Waiver justifications for ecotoxicology and environmental fate studies for indoor use of 1-MCP formulations were previously submitted with the EthylBloc technology (0.14% 1-MCP) food-use label amendment petition (Longacre, 2000; MRID not known), and are contained in this petition as well.

### Additional Items:

An FQPA Notice of Filing for 1-MCP on post-harvest fruit and vegetables (MRID 450396-1) was submitted in April, 2000 as part of the 1-MCP exemption from tolerance petition. This Notice of Filing was published in the Federal Register on 21Jun00. It is our conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to I-MCP residues to the US population, including infants and children.

A tolerance fee of \$12,550, as specified in the 1999 EPA tolerance fee schedule for an exemption from the requirement of a tolerance [Federal Register, 64 (101); 26May99; p 28386; Sec 180.33(c)], was sent to EPA's Headquarters Accounting Operations Branch in April, 2000 in support of the previously submitted exemption from tolerance petition.

No Formulator's Exemption is needed since 1-MCP is synthesized in an *in situ* process during the manufacture of SmartFresh by Rohm and Haas Company.

Please assign MRID numbers to the new reports submitted in support of this application, and please contact me by phone (215-592-2078), fax (215-592-3414), or e-mail (mah55y@rohmhaas.com) if you have any questions about this submission.

Drunt Lark

Robert H. Larkin, Ph.D.

Director, Agricultural Chemicals

Registration and Regulatory Affairs Department

Sheryl Reilly / EPA BPPD

CC:

Mr. Benmhend 28June01 Page 3

## Attachments (reports in triplicate):

	Guideline Reference Number	Rohm and Haas Company Report Number	Report Title	MRID
٠	Series 830 Group A	APR-01-068	J. C. Crawford; Product Chemistry Series 830 Group A: Product Identity, Composition, and Analysis of 1-MCP Formulation; 17May01	45458601
2.	Series 830 Group A	TM-2000-245-01	W. Hu; Determination of AI and Impurities in 1-MCP Formulation by Capillary Gas Chromatography; 18Dec00	REJ(M)
3.	Series 830 Group A	APR-01-018	W. Hu; Product Chemistry Series 830 Group A: Product Identity, Composition and Analysis of 1-MCP Formulation - GLP Analysis of Five Representative Batches of 1- MCP Formulation; 26Apr01	REJ(OD)
•	Series 830 Group A	A. Product Identity Composition and		REJ(\$3)
	Series 830 Group A	APR-01-017	W. Hu; GLP Validation of Test Method TM-2000-245-01; 19Mar01	45458602
•	Series 830 Group B	APR-01-069	J. C. Crawford; Product Chemistry Series 830 Group B: Physical and Chemical Characteristics of 1-MCP Formulation; 27Apr01	45450103
•	152-11 (OPPTS 870.1200)	00R-200	J. R. Parno, L. P. Craig, and S. L. Eberly; 1- Methylcyclopropene Alpha-Cyclodextrin Complex (3.3% a.i.): Acute Dermal Toxicity Study in Male and Female Rats; 08Feb01	4545860
	152-14 (OPPTS 870.2500)	00R-201	J. R. Parno, L. P. Craig, and S. L. Eberly; 1-Methylcyclopropene Alpha-Cyclodextrin Complex (3.3% a.i.): Skin Irritation Study in Rabbits; 08Feb01	45458605

Mr. Benmhend 28June01 • Page 4

#### (Continued):

	PPTS 0.2400)	00R-202	J. R. Parno, L. P. Craig, and S. L. Eberly; 1- Methylcyclopropene Alpha-Cyclodextrin Complex (3.3% a.i.): Eye Irritation Study in Rabbits; 08Feb01	4545866	
152- (OP 870		00R-203	J. R. Parno, D. M. Anderson, and T. L. Danberry; 1-Methylcyclopropene Alpha-Cyclodextrin Complex (3.3% a.i.): Dermal Sensitization Study in Guinea Pigs - Maximization Test; 07Feb 01	45458607	* * * * * * * * * * * * * * * * * * *
1	2-23 PPTS 0.3700)	00R-181	S. L. Wood, L. P. Craig, H. J. Bernacki, and T. L. Danberry; 1-Methylcyclopro- pene: Inhalation (Whole Body) Develop- mental Toxicity Study in Rats; 18Apr01	4545868	notion

Administrative materials submitted with this letter:

- 1) EPA Form 8570-1 (OPP Identifier 250087);
- 2) Petition binder containing Sections A, B, C, D, E, F, G, I and J; plus Data Matrix Tables (new and previously submitted studies);
- 3) EPA Form 8570-34: Certification with Respect to Citation of Data;
- 4) Proposed Label for 71297-\_ (Post-Harvest Fruits and Vegetables; Sec 3(2) RHL; 28June01) (5 copies).



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

### SEP 2 | 2001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Robert H. Larkin, Ph.D.
Director, Agricultural Chemicals
Registration and Regulatory Affairs Department
Agrofresh, Inc./Rohm and Haas Company
100 Independence Mall West
Philadelphia, PA 19106

Subject:

Pending application 71297-E, your application dated June 28, 2001,

received by the Agency.

Product Name: SmartFresh<sup>TM</sup>

Dear Mr. Larkin:

All data submitted to the Agency to support registration actions must conform to a standard format, organization, and other requirements described in Pesticide Registration Notice (PRN) 86-5 dated July 29, 1986. This notice was mailed to all registrants on record with the Agency at that time and is currently available on the Internet (www.epa.gov/PR\_Notices/).

All incoming data are screened for compliance with the PR Notice. Data that are in compliance are assigned Master Record Identification Numbers (MRIDs), microfilmed and forwarded for appropriate action. Data that do not comply with the requirements of the Notice are not admitted into the system. Such data must be brought into compliance with the PR Notice before the data can be given further consideration in support of the regulatory action for which the data were submitted.

The data submitted in connection with the proposed action listed above have been found deficient with respect to the requirements of PRN 86-5. The deficiencies are identified in the enclosed comments from the Information Services Branch of the Program Management and Support Division.

Biopesticides and Pollution Prevention Division will hold associated documents for 75 days to give opportunity to resubmit the supporting data in acceptable form. If you have not done so by that time, the application and other associated documents may be administratively withdrawn from further consideration without notice to you, in accordance with policies established by PR Notice 75-4 dated August 27, 1975.

Should you wish to pursue the registration of your product after the application has been withdrawn you will have to submit a complete new application.

If you choose to resubmit your data you should enclose a copy of this letter and the enclosure to identify the data as a corrected resubmission of data previously found deficient with respect to PRN 86-5. Only resubmit those items of data for which no MRID numbers were assigned. If any of your previous items was assigned an MRID number, do not resubmit that particular item of data, but simply refer to it by title and by the assigned MRID number.

Should you have any questions, please feel free to contact Driss Benmhend at (703) 308-9525.

Sincerely,

Sheryl K. Relly, Ph.D., Chief

Biochemical Pesticides Branch

Biopesticides and Pollution Prevention

Division (7511C)

Enclosure

cc: Driss Benmhend, RAL

AGROFRESH, INC./ROHM AND HAAS COMPANY 100 INDEPENDENCE MALL WEST PHILADELPHIA, PA 19106

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 07/03/01. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

#### Rejected study [01] :

\* No title page was included for this study.

You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

#### Rejected study [02] :

\* Each study which contains a claim of confidentiality

under FIFRA 10(d)(1)(A),(B) or (C) must be prepared with a releasable part of the study as well as a confidential attachment. The releasable part of the study must contain a title page, confidentiality claim statement, any data not protected by the above mentioned FIFRA section and cross reference(s) to protected data which can be found in the confidential attachment. See p. 8 of PR Notice 86-5.

### Rejected study [03] :

\* Each study which contains a claim of confidentiality under FIFRA 10(d)(1)(A),(B) or (C) must be prepared with a releasable part of the study as well as a confidential attachment. The releasable part of the study must contain a title page, confidentiality claim statement, any data not protected by the above mentioned FIFRA section and cross reference(s) to protected data which can be found in the confidential attachment. See p. 8 of PR Notice 86-5.

## HISTORY

June 28, 2001 - Delivered Studies to EPA

Sep. 21,2001 - EPA notified AgroFresh that 3 studies were rejected under PR 86-5

Oct. 9, 2001 - Agrofrush wrote that rejected studies were not meant to stand alone, but are included as Appendices to Series 830 Group A (mRID 45458601)

Dec, 2001 - Letter of Oct. 9, 2001 is returned to AgroFresh as "undeliverable"

Jan. 2, 2002 - Agrofresh resubmits Letter of Oct 9, 2001 using new address (Washington, DC instead of Ailington, VA)

MAY 15, 2002

TO: DRISS BENMHEND U.S. EPA

FAX: 703-308-7026

RE: AGROFRESH/ROHM AND HAAS SUBMISSION OF JUNE 28, 2001

FROM:

GEORGE A. HAZELTON, Ph.O.

SENIOR TOXICOLOGIST

ROHM AND HAAB COMPANY
RESEARCH LABORATORIES
727 NORRISTOWN ROAD PO BOX 804
SPRING HOUSE PENNSYLVANIA 19477-0806
(215) 641-7473 FAX. (215) 618-1621
E-MAIL RSTOGH@ROHMHAAS.COM



96%

#PAGES = 10

## BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen	REVIEWER: Driss Blumberd (ASSIGNED BY: 562
EPA REG./FILE SYMBOL #29	OF6144
ACTION CODE 232	
(NEW a.i./EUPs/Tolerances: Yes_	No
SUBMISSION BARCODE	and he
TATE ON APPLICATION 4-11-0	(mcP)
EPA RECEIVED DATE 4-12-00	
PM RECEIVED DATE 4-21-0a	
ASSIGNED IN PRAT: YES	NO
COMPLETED BY: T. O. CHEA	DATE: 4/24/00
	\$ <mark>\$00000000000000000000000000000000000</mark>
TINAL ACTION	
Response Code	
Response Date:	
MOS:(1) Cite-All	C + 5
(4) Not Applical	ole Service Se
(8) Selective	antener
CRP: Yes	No
Restricted Use: Yes	No Services on
Manufacturing Use: Yes	No
Evalusiya Usar	No.

129

REPLY TO: RESEARCH LABORATORIES 727 NORRISTOWN ROAD, P.O. BOX 904 SPRING HOUSE, PA 19477-0904 (215) 841-7000 FAX (215) 841-7857 ROHN HARS

March 7, 2002

Mr. Driss Benmhend
Biopesticides and Pollution Prevention Division
U. S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Dear Mr. Benmhend:

Re: December 6, 2001 Preregistration Meeting
EthylBloc Technology (EPA Registration No. 71297-1)
SmartFresh™ (EPA File Symbol 71297- E)

The attendees of the December 6 meeting were as follows.

AgroFresh Inc. (a subsidiary of Rohm and Haas Company)

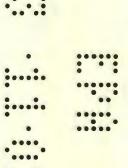
George Hazelton, Toxicologist Kathy Krueger, Business Director Bob Larkin, Regulatory Director

#### **BPPD**

Roger Gardner Russell Jones Driss Benmhend Sheryl Reilly

The purpose of the meeting was to summarize the exposure and toxicology data that have been generated in support of the pending tolerance exemption petition for 1-methylcyclopropene (1-MCP), the active ingredient in EthylBloc Technology and SmartFresh<sup>TM</sup>, and in support of the pending food use applications for EthylBloc Technology and SmartFresh<sup>TM</sup>. The studies containing the data were subsequently hand delivered to the front end processing desk in Crystal Mall #2 on December 14, 2001. With this submission, all of the studies requested by BPPD in support of the above petition and registration applications have been completed.

The agenda and overheads presented at the December 6 meeting are attached. The information was well received by BPPD. AgroFresh was complimented for the



thoroughness of their efforts and for the approach utilized in assessing the risks of 1-MCP to workers and to consumers.

Timing for the review and approval process was discussed. AgroFresh's target is to initiate commercial sales for the 2002 apple harvest which begins in mid-August. Since printing of labels and obtaining of key state registrations will take a minimum of sixty days, we are requesting an expedited review and approval by BPPD by June 1, 2002. BPPD explained that they have a large backlog of work and could not commit to meet this target. They will try their best but stated that meeting the June 1 target will be a real stretch for them. AgroFresh requested that BPPD give first priority to approval of the newer 3.3% formulation of 1-MCP, brand name SmartFresh<sup>TM</sup>.

#### **Action Points:**

- 1. AgroFresh to hand deliver studies to Front End Processing Desk (done December 14, 2001).
- 2. D. Benmhend to send electronic template for tolerance approval to R. Larkin (done December 7, 2001).
- 3. R. Larkin to send draft summary of meeting to D. Benmhend for agreement (done with this submittal).
- 4. R. Larkin to send D. Benmhend update of data matrix (done March 6, 2002), Notice of Filing and labels for EthylBloc Technology and SmartFresh™.

Thank you for arranging the meeting. We appreciated the opportunity to discuss this novel and exciting technology. We are committed to provide any additional information to help expedite your review and approval process to make this technology available to the apple industry for the 2002 harvest.

Sincerely,

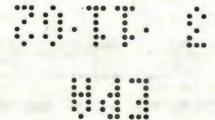
Robert H. Larkin

Technical and Regulatory Director

enclosures

## Agenda

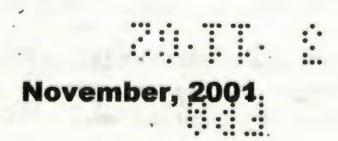
- Review technology
- · Pending regulatory actions
- Additional information requested
- CMP study and residue study
- · Update toxicology database and risk assessments
- Administrative information update
- Timelines for BPPD review/approval





# AgroFresh Inc.

a Rohm and Haas company



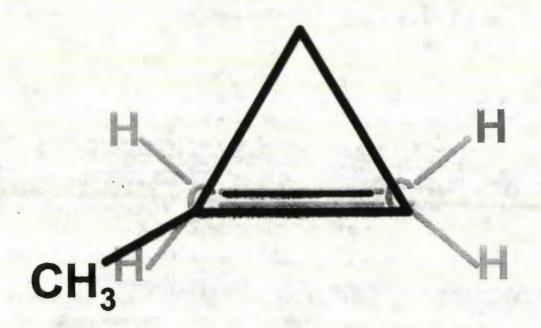


EthylBloc

MCP 1 methylevelopropene

MCP binds to the ethylene receptor site blocking its action

# EthylBloc<sup>®</sup>



1-MCP: 1-methylcyclopropene

# EthylBloc® Product Concept

Extremely Low Use Rate

Banana and tropical fruit: 10-100 ppb

Pome fruit and vegetables: 100-1000 ppb

Applied as a Gas in a Sealed Storage Room or Shipping Container (Similar & Ethylene)

Gas Released From Power by Adding Water, Buffer, or Surfactant

Single Exposure of 2–24 Hr Duration Depending on Release Temperature

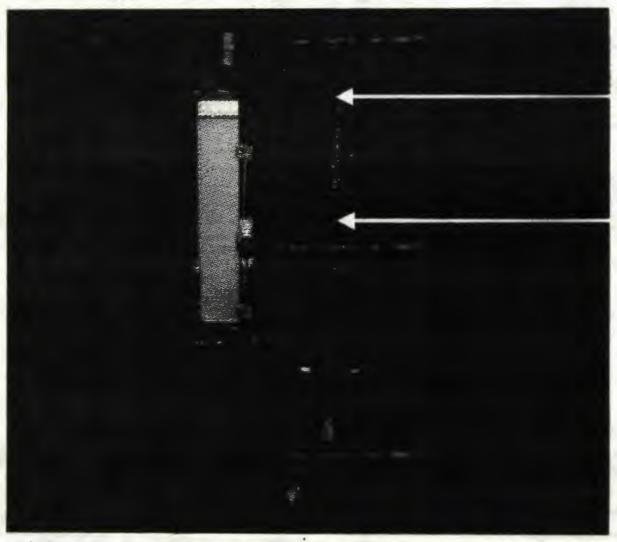
Normal Storage or Shipping Conditions Applied After Exposure

## Formulations

- 0.14% MCP EthylBloc™
- 3.3% MCP SmartFresh<sup>™</sup>
- Other components are
- Powder can be manually or automatically mixed with water to release 1-MC
- AgroFresh. Inc. is subsidiary name, a subsidiary of Rohm and Haas Company



## **SmartFresh™ Generator**



SmartFresh<sup>TM</sup> Released into Storage Room

Water + SmartFresh<sup>TM</sup>
Powder





Treating an Apple Room



**SmartFresh** Generator





# Treatment Procedure is Very Simple

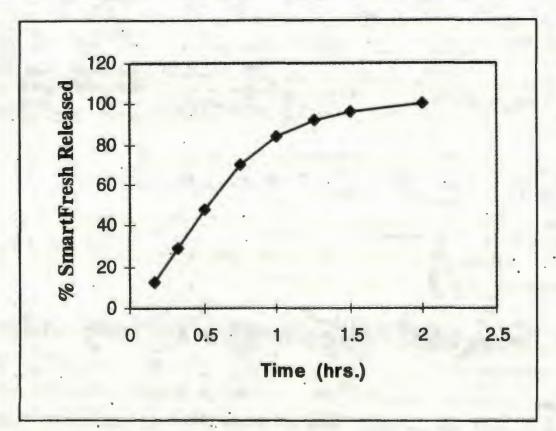
- Choose an apple storage room, such as a CA room, that is air-tight. Make sure the door can be sealed well. This insures that treatment will be efficacious.
- A SmartFresh generator is placed in the filled storage room.
- · Water is added to the generator and it is turned on.
- Operator exits the room and seals the door.
- SmartFresh releases after operator exits the room.
- Treatment time is 18-24 hours, followed by opening the door to vent the room for 15 minutes.





## Commercial Scale SmartFresh™ Release Profile

Even at large scale, SmartFresh<sup>TM</sup> releases quickly to ensure uniform and complete treatment of fruit





# Pending Actions Food Use

- Registration Application for EthylBloc Technology (0.14%) – submitted 4/6/2000
- Petition For Exemption From Tolerance for 1-MCP (OF 6144) – submitted 4/6/2000
- Registration of SmartFresh (3.3%) submitted 6/28/2001

# Additional Information Requested

- Science Review dated February 21, 2001
- Residue study on apples
- Acute and subchronic inhalation studies on 1-MCP
- Analysis for CMP in treated storage chamber
- Mutagenicity studies on 1-MCP gas

## Status Of Additional Information

- Mutagenicity studies on 1-MCP gas submitted 4/6/2001
- Acute inhalation study on I-MCP gas submitted 4/6/2001
- Preliminary residue results submitted 4/6/2001
- Subchronic inhalation study, final residue report and CMP chamber study completed - to be submitted shortly

## CMP Chamber Study

- Empty tractor trailer used as surrogate treatment room
- 1-MCP released by prototype commercial generator
- Room air analyzed for 1-MCP and for CMP
- Ratio of CMP to 1-MCP determined to be the same as ratio in 1-MCP technical
- CMP concentration in room = 0.65 ppb

# Residue Study Background

- Theoretical maximum residue in apples = 9 ppb at 1000 ppb max use rate
- Targeted for detection limit of 1 ppb
- Below level of detection of conventional analytical techniques, therefore used C-14labeled 1-MCP

# Residue Study Design

- Four apple varieties Gala. Fuji, Red Delicious, Golden Delicious
- Treatment chamber approximately one cubic meter
- Two temperatures 0 and 20 degrees
- 1200 ppb treatment rate
- Sampling times out to 7 days after treatment

## **Summary of Sample Residues**

Apple Variety	Average residue mg/kg	Min. Residue mg/kg	Max. Residue mg/kg	Number of Samples
Red Delicious	0.00341	0.00114	0.00598	21
Gala	0.00510	0.00224	0.00911	15
Granny Smith	0.00398	0.00182	0.00737	12
Fuji	0.00324	0.00142	0.00474	12
Overall	0.00391	0.00114	0.00911	60

# Residue Study Conclusions

- Average Residue for 8 treatments = 3.9 ppb
- Residue less than 40% of theoretical max
- Residue independent of temperature, variety, position in chamber, time after treatment
- Residue below detection limits of conventional analytical techniques and below level that can be identified
- Apples are worst case for magnitude of residue for proposed crops

CROP	MAX USE/RATE PPB	MAX USE/RATE MG AI/M3	PACK DENSITY KG/M3	MAX RESIDUE PPB
APPLE	1000	2.24	250	8.96
PEARS	500	1.12	250	4.48
AVOCADO	300	0.67	145	4.63
MELONS	1000	2.24	257	8.72
CUCUMBERS	1000	2.24	250	8.96
TOMATOES	500	1.12	225	4.98

# Information To Update?

- Tolerance Exemption Petition
- Notice of Filing
- Data Matrix
- Labels

# 1-Methylcyclopropene: Summary of Toxicology Studies

# **Acute Toxicity Studies**

# 3.3% a.i. Formulation (cyclodextran complex):

Study	Result
Oral LD50 (rat)	>5000 mg/kg (limit dose);
	No clinical signs of toxicity.
Dermal LD50 (rat)	>5000 mg/kg (limit dose);
	No clinical signs of toxicity.
Inhalation LC50 (rat)	> 1126 ppm a.i. (or > 2.5 mg a.i/L);
"1-MCP gas tested"	No clinical signs of toxicity.
Skin Irritation (rabbit)	Mild irritation.
Eye Irritation (rabbit)	Mild irritation.
Dermal Sensitization (guinea pig)	Not a sensitizer, no labeling required.

Conclusion: 1-methylcyclopropene produces minimal to no acute toxicity.

# 1-Methylcyclopropene: Summary of Toxicology Studies

# **Mutagenicity Studies**

1-methycyclopropene (gas phase studies):

Ames Mutagenicity Assay (5 bacterial strains, tested as gas up to 1000 ppm a.i.)	Negative (not mutagenic)
Mammalian Point Mutation Assay (CHO cells, tested as gas up to 1000 ppm a.i.)	Negative (not mutagenic)
In Vitro Cytogenetics Assay (human lymphocytes, tested as gas up to 1000 ppm a.i.)	Negative (not mutagenic)
In Vivo Mouse Micronucleus Assay (tested up to 1000 ppm a.i., 6hr exposure)	Negative (not mutagenic)

Supplemental Data: 1-MCP was not mutagenic in Ames Assay and Mouse Lymphoma Forward Mutation Assay, when 1-MCP was suspended in cell media; and the compound was not mutagenic in *In Vivo* Mouse Micronucleus Assay, when 1-MCP complex was dosed orally by gavage.

Conclusion: 1-methylcyclopropene is not mutagenic.

# 1-Methylcyclopropene: Summary of Toxicology Studies (continued)

# **Developmental Toxicity Study in the Rat**

# 1-Methylcyclopropene exposure by inhalation:

Dose	Findings
107 ppm a.i.; 0.24 mg a.i./L [56 mg a.i./kg/day; 6 hr exposure/day]	No maternal or developmental toxicity <sup>a</sup> ,  NOEL for maternal toxicity
329 ppm a.i; 0.72 mg a.i/L [174 mg a.i/kg/day; 6 hr exposure/day]	No developmental toxicity <sup>a</sup> ,  Maternal toxicity: low incidence of enlarged spleens.
1029 ppm a.i; 2.3 mg a.i/L [543 mg a.i./kg/day; 6 hr exposure/day]	No developmental toxicity <sup>a</sup> ,  NOEL for developmental toxicity, <sup>a</sup> Maternal toxicity: minimal decrease in body weight gain, and high incidence of enlarged spleens.

No effects on fetal development and no evidence of soft tissue or skeletal malformations.

# **Conclusion:**

1-methylcyclopropene does not produce developmental toxicity.

The No-Observable-Effect Level (NOEL) for maternal toxicity was 107 ppm (or 56 mg/kg/day) and is the toxicological endpoint for short term exposure.

# 1-Methylcyclopropene: Summary of Toxicology Studies

# Multiple Dose Study (3-Months) in the Rat

# 1-Methylcyclopropene exposure by inhalation:

Test Concentration (Dose)*	Findings
24 ppm (0.05 mg/L)	No systemic toxicity <sup>b</sup> ,
[9-15 mg a.i./kg/day]	NOEL for study.
107 ppm (0.24 mg/L)	Effects on:
[39-66 mg a.i./kg/day]	spleen histopathology <sup>a</sup> (related to anemia), and
	kidney histopathology <sup>b</sup> (related to metabolism/excretion of 1-MCP).
1031 ppm (2.3 mg/L)	Effects on:
[380-640 mg a.i./kg/day]	hematology parameters (mild regenerative anemia);
•	spleen weight and histopathology <sup>a</sup> (related to anemia);
	kidney weight and histopathology <sup>b</sup> (related to metabolism/excretion of 1-MCP); and
	liver weight and histopathology <sup>c</sup> (related to metabolism/excretion of 1-MCP).

a- Spleen histopathology: yellow brown pigment, red pulp congestion, extramedullary hematopoiesis.

Conclusion: The No-Observable-Effect Level (NOEL) for subchronic toxicity was 24 ppm (or 9-15 mg/kg/day) and is the toxicological endpoint for long term exposure.

b- Kidney histopathology: intracytoplasmic eosinophilic structures and nuclear enlargement in epithelium of cortical tubules and pigment in these cells.

c- Liver histopathology: centrilobular hepatocellular hypertrophy.

# 1-Methylcyclopropene: Summary of Hazard Information

- No toxicity following acute exposure.
- Not mutagenic.
- Not a developmental toxicant.
- No toxicity to respiratory tract following single or multiple exposures.
- No evidence of neurotoxicity following single or multiple exposures.
- No effects on the pathology of any endocrine or reproductive organs following multiple exposures.
- Produces minimal to mild effects on hemopoietic system (mild regenerative anemia) and on organs related to metabolism/excretion of the compound (liver and kidney) following multiple exposures.
- No-Observable-Effect Levels (NOELs) for short term and long term exposures are 56 mg/kg/day and 9 to 15 mg/kg/day, respectively.

# Estimate of Risk to Worker

Hazard (toxicology endpoints) X Exposure = Risk

# 1. Toxicological endpoints:

Parameters for rat: Short term NOEL: 56 mg/kg/day, from developmental

toxicity study, and assumes 300g rat inhales 0.2 L/min. for

360 min. and absorption factor of 1.0 {107,000 ppb or

0.24 mg/L.

Long term NOEL: 9 mg/kg/day, from 3-month toxicity study, and assumes 440g rat inhales 0.2 L/min. for 360 min. and absorption factor of 1.0 {24,000 ppb or 0.053

mg/L}.

Parameters for human: 70 kg body weight.

21 L/min. (10 M<sup>3</sup> per 8 hour day, activity light work).

Exposure period of 15 or 240 min.

Absorption factor of 1.0 (or 100% absorption).

# 2. Exposure:

Exposure modeling using EPA's Industrial Source Complex Dispersion Model.

Controlled atmosphere (CA) apple storage facility (1824 m³).

Maximum use concentration of 1000 ppb 1-MCP.

Following treatment of apples, room vented at rate of 0.75 air changes/hr.

Effect of air changes on 1-MCP concentration in CA room.

Post-Venting Air Change (hr	I-MCP Conc (ppb v/v)
0 (0.0)	1000
1 (1.3)	368
2 (2.7)	135
3 (4.0)	50
4 (5.3)	18
5 (6.7)	7

# Estimate of Risk to Worker

Evaluation of Margin of Safety (MOS) for the Worker:

MOS = Ratio of No-Observable-Effect Level (NOEL) to Exposure.

MOS for Worker Exposure should be >100.

# **Exposure Scenarios:**

Scenario #1: 15 minute accidental exposure to 1000 ppb conc. of 1-MCP.

(i.e., maximum use rate).

1000 ppb equivalent to 0.0022 mg/L

 $0.0022 \text{ mg/L} \times 21 \text{ L/min.} \times 15 \text{ min.} + 70 \text{ kg person} = 0.0099 \text{ mg/kg}$ 

MOS: NOEL (short term) + exposure =  $56 \text{ mg/kg} + 0.0099 \text{ mg/kg} = \underline{5656}$ 

Scenario #2: 4 hour exposure to 50 ppb conc. of 1-MCP

(i.e., worker spends 1/2 day in room exposed to residual

levels of 1-MCP).

50 ppb equivalent to 0.00011 mg/L

 $0.00011 \text{ mg/L} \times 21 \text{ L/min.} \times 240 \text{ min.} + 70 \text{ kg person} = 0.00792 \text{ mg/kg}$ 

MOS: NOEL (long term) + exposure = 9 mg/kg + 0.00792 mg/kg = 1136

# Estimate of Risk to Consumer (Dietary Exposure)

Hazard (toxicology endpoints) X Exposure = Risk

- 1. Toxicological endpoints: Chronic dietary exposure- 9 mg/kg/day; Acute dietary exposure- 56 mg/kg/day.
- 2. Dietary Exposure: = Amount of Food Consumed X Residue in Food (<10 ppb).

## Amount of Food Consumed Determined:

Food consumption (chronic and acute) was determined using Dietary Evaluation Estimation Model (DEEM), which incorporates food consumption values (1992-1996) for a number of population subgroups (i.e, adults, children, infants).

#### Residue Data:

# Summary of Residues of 1-MCP in Different Apple Varsities

[All values are adjusted for maximum use rate of 1000 ppm a.i. (v/v)]\*

Apple Variety	Average residue	Min. Residue	Max. Residue	Number of Samples
Red Delicious	2.8	1.0	5.0	21
Gala	4.3	1.9	7.6	15
Granny Smith	3.3	1.5	6.1	12
Fuji	2.7	1.2	4.0	12
Overall	3.3	1.0	7.6	60

<sup>\*</sup>Residue studies were conducted using an application rate of 1200 ppm 1-MCP (v/v); however, the maximum use rate on the label will only be 1000 ppm 1-MCP (v/v). Residue values were adjusted using the following factor- 0.833 (or 1000/1200)<sup>18</sup>.

# Estimate of Risk to Consumer (Dietary Exposure)

10 ppb is a worst-case default for each food commodity, since the theoretical maximum residue concentration is 9 ppb or less.

# Example (for apples):

Max. Residue Conc. = max. use rate (mg a.i/m<sup>3</sup> + packing density (kg/M<sup>3</sup>)

Assumes all 1-MCP released ends up in apples.

Apples: 2.24 mg a.i./ $M^3 + 250 \text{ kg/}M^3 = 0.0089 \text{ mg } 1\text{-MCP/kg apples}$  (or 9 ppb)

# Theoretical maximum residue concentration for each commodity:

Commodity	Maximum use rate (ppb)	Maximum use rate (mg a.i./M³)	Packing density (kg/M³)	Maximum Residue (ppb)
Apples	1000	2.24	250	9.0
Pears	500	1.12	250	4.5
Avocadoes	300	0.67	145	4.6
Melons	1000	2.24	257	8.7
Cucumbers	1000	2.24	250	9.0

# Assumptions for dietary risk calculations:

- 1. 10 ppb (or 0.01 mg/kg) was assumed for all the food commodities (i.e., apples, pears, avocadoes, melons and cucumbers).
- 2. 100% of all food commodities were treated with 1-MCP.
- 3. No loss of residue with storage or further processing and handling of the fruits or vegetables.

# Estimate of Risk to Consumer (Dietary Exposure)

Dietary Exposure = Amount of Food Consumed X Residue in Food (<10 ppb).

Margin of Safety (MOS) = Ratio of No-Observable-Effect Level (NOEL) to Exposure.

# Total predicted chronic dietary exposure to 1-MCP:

Population Subgroup	Total Exposure* (mg a.i./kg body wt./day)	Margin of Safety**		
Adults (U.S. population)	0.000018	500,000		
All infants (<1 year)	0.000088	102,273		
Nursing infants	0.000043	209,302		
Non-nursing infants	0.000101	89,109		
Children 1-6 years	0.000081	111,111		
Children 7-12 years	0.000023	391,304		

<sup>\*</sup> Total exposure (chronic dietary) was determined by using food consumption values from DEEM Chronic analysis system and assuming a residue level of 10 ppb (or 0.01 mg/kg) for apples, pears, melons (all types), cucumbers and avocadoes.

# Total predicted acute dietary exposure to 1-MCP:

Population Subgroup	99.9 <sup>th</sup> Percentile  Exposure*  (mg a.i./kg body wt./day)	Margin of Safety**
Adults (U.S. population)	0.000711	78,762
All infants (<1 year)	0.001139	49,166
Nursing infants	0.000944	59,322
Non-nursing infants	0.001138	49,209
Children 1-6 years	0.001109	50,496
Children 7-12 years	0.000405	138,272

<sup>\*</sup> The 99th percentile exposure (acute dietary) was determined by using food consumption values from DEEM acute analysis system and assuming a residue level of 10 ppb (or 0.01 mg/kg) for apples, pears, melons (all types), cucumbers and avocadoes.

Margin of safety- NOEL of 9 mg/kg/day divided by predicted total exposure.

<sup>&</sup>quot;Margin of safety- NOEL of 56 mg/kg/day divided by predicted total exposure.

# Worker Risk to 3-Chloro-2-methylpropene

# 3-Chloro-2-methylpropene (CMP):

- Raw material in the synthesis of 1-methylcyclpropene (1-MCP).
- CMP is weakly mutagenic.
- CMP was carcinogenic in laboratory animal studies (i.e., in the forestomach of rats and mice, CMP produced squamous cell papillomas and/or carcinomas at 150 and 100 mg/kg/day, respectively, when administered by oral gavage.
- CMP is present in 1-MCP at no more than 0.08%.
- Recent experiments have verified that a treatment room containing 1000 ppb v/v 1-MCP will contain a maximum of only 0.8 ppb v/v of the impurity, CMP.

# Exposure scenario:

A worker may be accidentally exposed for 15 minutes to a maximum 1000 ppb 1-MCP or a concentration of 0.8 ppb of CMP (equivalent to 0.000003 mg/L).

# Exposure:

 $0.000003 \text{ mg/L} \times 21 \text{ L/min.} \times 15 \text{ min.} + 70 \text{ kg person} = 0.0000135 \text{ mg/kg}$ 

# Margin of Safety:

100 mg/kg + 0.0000135 mg/kg = >7,000,000

#### Conclusion:

There is minimal to no exposure to CMP, and thus negligible risk to workers from CMP when treating rooms with 1-MCP.

DP BARCODE: D281146

CASE: 063215

DATA PACKAGE RECORD

SUBMISSION: S610458

BEAN SHEET

DATE: 02/25/02 Page 1 of 1

\* \* CASE/SUBMISSION INFORMATION \*

CASE TYPE: REGISTRATION

ACTION: 306 RESUBMISSION

CHEMICALS: 224459 Cyclopropene, 1-methyl- (7CI, 8CI, 9CI) (CA INDEX NAM 0.1400%

ID#: 071297-00001 ETHYLBLOC COMPANY: 071297 AGRO FRESH INC.

PRODUCT MANAGER: 90 JANET ANDERSEN

703-308-8128 ROOM: CS1 5TH FL

PM TEAM REVIEWER: DRISS BENMHEND 703-308-9525 ROOM: CS1 5TH I

RECEIVED DATE: 02/12/02 DUE OUT DATE: 08/11/02

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 281146 EXPEDITE: Y DATE SENT: 02/25/02 DATE RET.: / / CHEMICAL: 224459 Cyclopropene,1-methyl- (7CI,8CI,9CI) (CA INDEX NAME)

DP TYPE: 001

CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT
DIV: BPPD / / /
BRAN: BPPD-IO / / /
SECT: IO / / /
REVR: / / / /
CONTR: / / /

ADMIN DUE DATE: 07/15/02

NEGOT DATE: / / PROJ DATE: / /

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

Attached, you will find new data submitted in support of the tolerance exemption and food use amendment of the product EthylBloc containing the active ingredient 1-Methylcyclopropene (MCP).

The following studies are attached:

- 1. Three Month Inhalation Tox. Study (in 2 volumes) MRID #456090-01
- 2. Apple Residue Study MRID #456090-02
- 3. Determination of 3-Chloro-2-Methylpropene Concentration in Chamber Treated with MCP MRID # 456090-03
- 4. Assessment of Worker and Consumer Risk MRID #456090-04

Please review and comment

Thanks

Driss

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC BRANCH/SECTION

DATE OUT DUE BACK

INS CSF

LABEL

5. Reilly

# FBPPD PRAT ACTION CODING FORM

REGISTRANT/COMPANY NAME:  ROHM and HAAS		Fast Tr Review Assign	rack: Yes DLIS red by UH	No. 10/02
EPA REG./FILE SYMBOL 71297.  ACTION CODE 306	- 1	[Note: I	f Fast Track, j change Revie in PRAT.]	vou may
(New A.I/EUP'S/Tolerances: Yes No DATE OF APPLICATION 2/8/0		rice	tael R	5 BMISZO
BPPD RECEIVED DATE 21140  SUBMISSION BARCODE 561045	12	Š		
ASSIGNED IN PRAT: Yes No DATE	2/16/02			
RAL RECEIVED DATE (RAL initials)	TE			
FINAL ACTION  RESPONSE CODE:	י גרי גרי ציי ציי גרי גרי גרי גרי.	אייי אייי אייי איי	ירי זה זה זה.	נר נר נרנד נר ער נר
MOS:(1) Cite All(4) Not Applicable(8) Selective	CRP Restricted Use: Manufacturing Use: Exclusive Use:	Yes   Yes   Yes   Yes	No   No	7



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

DRISS

308-9525

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

FEB - 6 2001

Mr. Robert Larkin 727 Norristown Road P. O. Box 904 Springhouse, PA 19477

Subject:

Pending Application EPA #71297-1 dated December 14, 2001

1-MCP Residues on Food commodities (Petition OF 06144)

Dear Mr. Larkin:

All data submitted to the Agency to support registration actions must conform to a standard format, organization, and other requirements described in Pesticide Registration Notice (PRN) 86-5 dated July 29, 1986. This notice was mailed to all registrants on record with the Agency at that time and is currently available on the Internet (www.epa.gov/PR\_Notices/).

All incoming data are screened for compliance with the PR Notice. Data that are in compliance are assigned Master Record Identification Numbers (MRIDs), microfilmed and forwarded for appropriate action. Data that do not comply with the requirements of the Notice are not admitted into the system. Such data must be brought into compliance with the PR Notice before the data can be given further consideration in support of the regulatory action for which the data were submitted.

The data submitted in connection with the proposed action listed above have been found deficient with respect to the requirements of PRN 86-5. The deficiencies are identified in the enclosed comments from the Information Services Branch of the Program Management and Support Division.

Biopesticides and Pollution Prevention Division will hold associated documents for 75 days to give opportunity to resubmit the supporting data in acceptable form. If you have not done so by that time, the application and other associated documents may be administratively withdrawn from further consideration without notice to you, in accordance with policies established by PR Notice 75-4 dated August 27, 1975.

Should you wish to pursue the registration of your product after the application has been withdrawn you will have to submit a complete new application.

If you choose to resubmit your data you should enclose a copy of this letter and the enclosure to identify the data as a corrected resubmission of data previously found deficient with respect to PRN 86-5. Only resubmit those items of data for which no MRID numbers were assigned. If any of your previous items was assigned an MRID number, do not resubmit that particular item of data, but simply refer to it by title and by the assigned MRID number.

Should you have any questions, please feel free to contact Mr. Driss Benmhend at (703) 308-9525.

Sincerely,

Sheryl K. Reilly, Ph.D., Chief Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511C)

Enclosure

### U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

AGROFRESH, INC./ROHM AND HAAS COMPANY 100 INDEPENDENCE MALL WEST PHILADELPHIA, PA 19106

Report of Analysis for Compliance with PR Notice 86-5

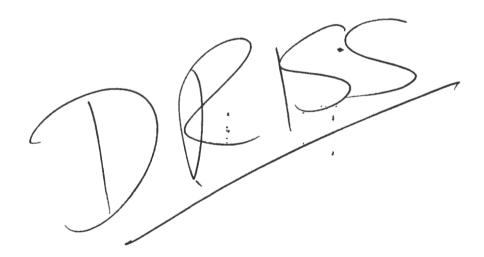
Thank you for your transmittal of 12/14/01. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

This an ACCEPTED submission

90

This is a PARTIALLY ACCEPTED/COMPLETELY REJECTED submission



Administrative

Materials

# TABLE ADDRESS: ROHMHAAS CENTRAL FAX (215) 592-3000

REPLY TO: RESEARCH LABORATORIES 727 NORRISTOWN ROAD, P.O. 80X 904 SPRING HOUSE, PA 18477-0904 [215] 641-7000 FAX (215) 641-7857



February 8, 2002

Ms. Linda Hollis BPPD US Environmental Protection Agency 1921 Jefferson Davis Highway CM-2 Arlington, VA 22202

Dear Ms. Hollis:

Re: EthylBloc Technology (EPA Registration No. 71297-1)
SmartFresh (EPA File Symbol 71297-E)
Corrected resubmission of data in response to Sheryl K. Reilly letter dated February 6, 2002 (enclosed)

Enclosed are corrected pages with the proper statement of confidentiality claims for the four studies identified as Rejected study (01), (02), (03) and (04) in the February 6 letter from Sheryl Reilly (enclosed). Each of these pages should replace the existing page 2 in each of the reports. The existing pages can be discarded. The replacement pages can be associated with the appropriate study by the study number at the top of each page. Thank you for your help.

Sincerely.

Robert H. Larkin. Ph.D.

Technical and Regulatory Director

enclosures

### U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

AGROFRESH, INC./ROHM AND HAAS COMPANY 100 INDEPENDENCE MALL WEST PHILADELPHIA, PA 19106

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 12/14/01. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

## Rejected study [01] :

\* You failed to sign the statement of data confidentiality claims included in the study.

# Rejected study [02]:

You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

# Rejected study [03] :

You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

# Rejected study [04] :

You must include one of the two acceptable statements

of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

# ROHIM

#### December 14, 2001

Document Processing Desk
Office Of Pesticide Programs (7504C)
U. S. Environmental Protection Agency
Mr. Driss Benmhend
Biopesticides and Pollution Prevention Division
Room 266A, Crystal Mall #2
1021 Jefferson Davis Highway
Arlington, VA 22202-4501

#### Dear Mr. Benmhend:

Subjects: EthylBloc Technology (EPA Registration No. 71297-1)

SmartFresh (EPA File Symbol 71297-E)

Active ingredient = 1-Methylcyclopropene (1-MCP)

Petition for Exemption From the Requirements of a Tolerance for 1-MCP residues on Food Commodities (Petition OF 06144)

Response To February 21, 2001 Science Review (Russel S. Jones to Driss Benmhend)

In the February 21, 2001 Science Review (Russel S. Jones to Driss Benmhend), a number of additional studies were requested to support the petition for a tolerance exemption for 1-MCP on food commodities and to support the proposed label amendment to EthylBloc Technology (EPA Registration No. 71297-1) to extend the use of 1-MCP to include food uses. Many of these studies were submitted previously (letter of April 6, 2001, S. Longacre to Driss Benmhend).

The final three studies requested in the February 21 Science Review are being submitted (three copies of each) with this letter. The studies are:

- 1. Rohm and Haas Company Report No. 00R-183, 1-Methylcyclopropene: 3-month Inhalation (Whole-body) Toxicity Study In Rats, J. S. Ferguson, E. M. Anderson and H. J Bernacki, Jr, October 19, 2001.
- 2. Rohm and Haas Technical Report No. AF-01-141, C-14 -1-Methylcyclopropene (1-MCP) Apple Residue Study, Dennis Verona, December 12, 2001.
- 3. AgroFresh Memorandum No. 01-143, Determination of 3-Chloro-2-Methylpropene Concentration in Chamber Treated with 1-Methylcyclopropene, Bret A. Snyder and Bridget M. Stevens, December 4, 2001.

In addition a report containing a revised risk assessment for 1-MCP for consumers and workers is also being submitted at this time.

4. Rohm and Haas Company Report No. 01R-1071, 1-Methylcyclopropene (1-MCP): Assessment of Worker and Consumer Risk, G.A. Hazelton, November 26, 2001.

The results of these four studies, combined with the results from the previously submitted studies, demonstrate that there are very large margins of safety associated with the proposed food uses of 1-MCP for both workers and consumers.

We believe that the data submitted previously and currently with this letter fully support approval of an exemption from tolerance for food use for 1-MCP and the approval for registration for use of 1-MCP for indoor use on harvested fruits and vegetables. We request that the Agency expeditiously review these studies and approve the associated petition for exemption from tolerance and grant the registrations so that this valuable product is available for use is available for use for the 2002 harvest season.

Please contact me if you have any questions or need any further information. I am available for discussion either by phone (215-641-7397) or in person.

Robert H. Larkin, Ph.D. Technical and Regulatory

Director

# 100 INDEIRENDENCE MALL WEST, PHILADELPHIA, PA 19106-2399 USA TELEPHONE (215) 592-3000 CABLE ADDRESS: ROHMHAAS CENTRAL FAX (215) 592-3377

REPLY TO: RESEARCH LABORATORIES 727 NORRISTOWN ROAD, P.O. BOX 904 SPRING HOUSE, PA 19477-0904 (215) 841-7000 FAX (215) 841-7857 ROHM HAAS

#### December 14, 2001

Document Processing Desk
Office Of Pesticide Programs (7504C)
U. S. Environmental Protection Agency
Mr. Driss Benmhend
Biopesticides and Pollution Prevention Division
Room 266A, Crystal Mall #2
1021 Jefferson Davis Highway
Arlington, VA 22202-4501

#### Dear Mr. Benmhend:

Subjects: EthylBloc Technology (EPA Registration No. 71297-1)

SmartFresh (EPA File Symbol 71297-E)

Active ingredient = 1-Methylcyclopropene (1-MCP)

Petition for Exemption From the Requirements of a Tolerance for 1-MCP residues on Food Commodities (Petition OF 06144)

Response To February 21, 2001 Science Review (Russel S. Jones to Driss Benmhend)

In the February 21, 2001 Science Review (Russel S. Jones to Driss Benmhend), a number of additional studies were requested to support the petition for a tolerance exemption for 1-MCP on food commodities and to support the proposed label amendment to EthylBloc Technology (EPA Registration No. 71297-1) to extend the use of 1-MCP to include food uses. Many of these studies were submitted previously (letter of April 6, 2001, S. Longacre to Driss Benmhend).

The final three studies requested in the February 21 Science Review are being submitted (three copies of each) with this letter. The studies are:

- 1. Rohm and Haas Company Report No. 00R-183, 1-Methylcyclopropene: 3-month Inhalation (Whole-body) Toxicity Study In Rats, J. S. Ferguson, E. M. Anderson and H. J Bernacki, Jr, October 19, 2001.
- 2. Rohm and Haas Technical Report No. AF-01-141, C-14 -1-Methylcyclopropene (1-MCP) Apple Residue Study, Dennis Verona, December 12, 2001.
- 3. AgroFresh Memorandum No. 01-143, Determination of 3-Chloro-2-Methylpropene Concentration in Chamber Treated with 1-Methylcyclopropene, Bret A. Snyder and Bridget M. Stevens, December 4, 2001.

In addition a report containing a revised risk assessment for 1-MCP for consumers and workers is also being submitted at this time.

Rohm and Haas Company Report No. 01R-1071, 1-Methylcyclopropene (1-MCP): Assessment of Worker and Consumer Risk, G.A. Hazelton, November 26, 2001.

The results of these four studies, combined with the results from the previously submitted studies, demonstrate that there are very large margins of safety associated with the proposed food uses of 1-MCP for both workers and consumers.

We believe that the data submitted previously and currently with this letter fully support approval of an exemption from tolerance for food use for 1-MCP and the approval for registration for use of 1-MCP for indoor use on harvested fruits and vegetables. We request that the Agency expeditiously review these studies and approve the associated petition for exemption from tolerance and grant the registrations so that this valuable product is available for use is available for use for the 2002 harvest season.

Please contact me if you have any questions or need any further information. I am available for discussion either by phone (215-641-7397) or in person.

Sincerely.

Robert H. Larkin, Ph.D. Technical and Regulatory

Director

Mr. Driss Benmhend
Biopesticides and Pollution Prevention Division
U. S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

I can't see discrepancies

Dear Mr. Benmhend:

Re: December 6, 2001 Preregistration Meeting
EthylBloc Technology (EPA Registration No. 71297-1)
SmartFresh (EPA File Symbol 71297- E)

The attendees of the December 6 meeting were as follows.

AgroFresh, Inc. (a subsidiary of Rohm and Haas Company)

George Hazelton, Toxicologist Kathy Krueger, Business Director Bob Larkin, Regulatory Director

#### **BPPD**

Roger Gardner Russell Jones Driss Benmhend Sheryl Reilly

The purpose of the meeting was to summarize the exposure and toxicology data that have been generated in support of the pending tolerance exemption petition for 1-methylcyclopropene (1-MCP), the active ingredient in EthylBloc Technology and SmartFresh, and in support of the pending food use applications for EthylBloc Technology and SmartFresh. The studies containing the data were subsequently hand delivered to the front end processing desk in Crystal Mall #2 on December 14, 2001. With this submission, all of the studies requested by BPPD in support of the above petition and registration applications have been completed.

The agenda and overheads presented at the December 6 meeting are attached. The information was well received by BPPD. AgroFresh was complimented for the thoroughness of their efforts and for the approach utilized in assessing the risks of 1-MCP to workers and to consumers.

Timing for the review and approval process was discussed. AgroFresh's target is to initiate commercial sales for the 2002 apple harvest which begins in mid-August. Since printing of labels and obtaining of key state registrations will take a minimum of sixty days, we are requesting an expedited review and approval by BPPD by June 1, 2002. BPPD explained that they have a large backlog of work and could not commit to meet

this target. They will try their best but stated that meeting the June 1 target will be a real stretch for them. AgroFresh requested that BPPD give first priority to approval of the newer 3.3% formulation of 1-MCP, brand name SmartFresh.

#### **Action Points:**

- 1. AgroFresh to hand deliver studies to Front End Processing Desk (done December 14, 2001).
- 2. D. Benmhend to send electronic template for tolerance approval to R. Larkin (done December 7, 2001).
- 3. R. Larkin to send draft summary of meeting to D. Benmhend for agreement (done with this submittal).
- 4. R. Larkin to send D. Benmhend update of data matrix, Notice of Filing and labels for EthylBloc Technology and SmartFresh.

Thank you for arranging the meeting. We appreciated the opportunity to discuss this novel and exciting technology. We are committed to provide any additional information to help expedite your review and approval process to make this technology available to the apple industry for the 2002 harvest.

Sincerely,

Robert H. Larkin Regulatory Director James Hollins

To: Driss Benmhend/DC/USEPA/US@EPA cc: Sheryl Reilly/DC/USEPA/US@EPA

01/18/02 11:14 AM

Subject: Re: Inquiries □

#### Driss,

I could not find a record of receipt for the two submissions you inquired about. If they were mailed through the postal system, they are probably still in Ohio getting irradiated. If they were sent by courier, under the names you listed, we have no record. Agri-Fos's submission must have been mailed, because 12/22/01 was on a Saturday.

Jim

#### Driss Benmhend



Driss Benmhend

01/18/02 09:36 AM

To: James Hollins/DC/USEPA/US@EPA

cc: Sheryl Reilly/DC/USEPA/US@EPA

Subject: Inquiries

I would like to know if you have the following submissions:

- 1. AgroFresh Co. EPA Reg. #: 71297-1 or Petition (0F6144). Applicant claims that they submitted data to FRP on 12/14/01
- 2. Agri-Fos Reg # 71962-R. According to the applicant submission was done on 12/22/01

Thanks for your assistance

Driss Benmhend United States Environmental Protection Agency Biopesticides and Pollution Prevention Division Biochemical Pesticides Branch (703) 308-9525

E-mail: benmhend.driss@epa.gov



editorial@fedweek.co

01/30/02 01:57 PM Please respond to Mike Causey Column Readers To: Driss Benmhend/DC/USEPA/US@EPA

cc:

Subject: Your Social Security & Medicare Benefits

Date: Wednesday, January 30, 2002

To: All Federal Agencies and Employees

RE: Your Social Security and Medicare Benefits

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

The Social Security/Medicare Handbook for Federal Agencies, Employees & Retirees--Only \$9.95 http://www.fedweek.com/Publications/default.asp

This comprehensive easy-to-follow guide is NOT a Dot Com download, government handout or pamphlet. It is a professionally printed publication that was written by our veteran team of experts with over 50 years of experience on your pay and benefits. Please continue reading...

\*\*\*\*\*\*\*\*\*\*

#### Dear Federal Employee:

Social Security and Medicare are easily the two most misunderstood benefits that federal employees, postal workers and retirees have. In years past, these employees didn't really need to know too much about these programs because they were under a separate retirement and disability benefits package, the Civil Service Retirement System, and didn't stand to get benefits from Social Security. Social Security and Medicare, largely were for somebody else--not them.

Not anymore. All that changed several years ago and these big changes in the benefits picture are just now hitting home for many federal employees and postal workers. With Social Security and Medicare now playing so important a role in your financial future, you can no longer afford to ignore them. It's vital that you understand just what types of benefits you're accumulating, what level of benefits you stand to receive, what provisions might reduce or even eliminate them, and how they interact with your other benefits—in sum, how to best position yourselves to get the most out of these two key programs.

Again, never before has there been such a huge need for this information. That's why FEDweek has published its new Social Security/Medicare Handbook for Federal Employees & Retirees. Until now, there has never been a comprehensive, easy-to-understand handbook for federal employees and retirees that fully explains not only those programs but

also how they dovetail (and, in some cases, conflict) with the federal government's retirement and health insurance programs. Take a look at a partial table of contents for this all-new handbook:

Section I: Social Security Overview Earning Credits Credit for Military Service Calculating Benefits The Windfall Elimination Provision The Government Pension Offset Social Security's Role In Federal Retirement Benefits Social Security's Role in Federal Retirement Decisions Family Benefits Survivors Benefits Social Security Disability Benefits Social Security and Federal Retirement Disability Benefits Supplemental Security Income After Benefits Begin The Earnings Test Taxation of Social Security Benefits Administrative Matters and Resources

Section II: Medicare
Overview
FEHB and Medicare
Medicare Part A
Medicare Part B
Managed Care (HMOs)
'Medigap' Policies
Private Fee-for-Service Plans
Rights, Protections and Appeals
Frequently Asked Questions
Resources

"This Social Security/Medicare Handbook fills a great need for federal agencies, employees and retirees. You'll find it very useful, informative and indispensable. And we prepared it just for you."

Don Mace, Publisher

\*\*\*\*\*\*\*\*\*\*\*

The Cost of The Social Security/Medicare Handbook for Federal Employees & Retirees is only \$9.95 (plus \$3.75 s&h) and you can order it directly through our "Publications" section of our website: http://www.fedweek.com/Publications/default.asp or by calling our 24 hour toll-free order line (888) 333-9335. You may also mail your order with payment (\$13.70) to: FEDweek, PO Box 5519, Glen Allen, VA 23058.

Group/Agency Discounts Available!
This publication is available in bulk quantities for federal agency distribution with quantity discounts. You can see the

quantity discounts on our website: http://www.fedweek.com/publications/quandisc.htm or ask one of our representatives about them when you call our order line (888) 333-9335.

FEDweek
Publisher, Don Mace
VP Marketing, Kevin Couch
Website: http://www.fedweek.com

You are currently subscribed to mike\_causey\_column as: benmhend.driss@epa.gov To unsubscribe send a blank email to leave-mike\_causey\_column-552045E@fedweek.sparklist.com

Mr. Robert Larkin 727 Norristown Road P. O. Box 904 Springhouse, PA 19477

Subject:

Pending Application EPA #71297-1 dated December 14, 2001

1-MCP Residues on Food commodities (Petition OF 06144)

Dear Mr. Larkin:

All data submitted to the Agency to support registration actions must conform to a standard format, organization, and other requirements described in Pesticide Registration Notice (PRN) 86-5 dated July 29, 1986. This notice was mailed to all registrants on record with the Agency at that time and is currently available on the Internet (www.epa.gov/PR Notices/).

All incoming data are screened for compliance with the PR Notice. Data that are in compliance are assigned Master Record Identification Numbers (MRIDs), microfilmed and forwarded for appropriate action. Data that do not comply with the requirements of the Notice are not admitted into the system. Such data must be brought into compliance with the PR Notice before the data can be given further consideration in support of the regulatory action for which the data were submitted.

The data submitted in connection with the proposed action listed above have been found deficient with respect to the requirements of PRN 86-5. The deficiencies are identified in the enclosed comments from the Information Services Branch of the Program Management and Support Division.

Biopesticides and Pollution Prevention Division will hold associated documents for 75 days to give opportunity to resubmit the supporting data in acceptable form. If you have not done so by that time, the application and other associated documents may be administratively withdrawn from further consideration without notice to you, in accordance with policies established by PR Notice 75-4 dated August 27, 1975.

			CONCURREN	ICES		
SYMBOL >	7511C	7511				
SURNAME	Pollard	Rull				***************************************
DATE	26/02	2/6/02				
EPA Form 1320-	1 (12-70)				OFFICIAL F	LE COPY 1 X 7

Should you wish to pursue the registration of your product after the application has been withdrawn you will have to submit a complete new application.

If you choose to resubmit your data you should enclose a copy of this letter and the enclosure to identify the data as a corrected resubmission of data previously found deficient with respect to PRN 86-5. Only resubmit those items of data for which no MRID numbers were assigned. If any of your previous items was assigned an MRID number, do not resubmit that particular item of data, but simply refer to it by title and by the assigned MRID number.

Should you have any questions, please feel free to contact Mr. Driss Benmhend at (703) 308-9525.

Sincerely,

Sheryl K. Reilly, Ph.D., Chief Biochemical Pesticides Branch

**Biopesticides and Pollution Prevention** 

Division (7511C)

Enclosure

# U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

AGROFRESH, INC./ROHM AND HAAS COMPANY 100 INDEPENDENCE MALL WEST PHILADELPHIA, PA 19106

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 12/14/01. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

### Rejected study [01] :

\* You failed to sign the statement of data confidentiality claims included in the study.

### Rejected study [02] :

You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

### Rejected study [03] :

You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

### Rejected study [04] :

You must include one of the two acceptable statements

of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

BPPD #7/297-1 #1/297-1

This an ACCEPTED submission

This is a PARTIALLY ACCEPTED/COMPLETELY REJECTED submission



Sheryl Reilly

06/11/01 04:35 PM

To: Driss Benmhend/DC/USEPA/US@EPA

cc:

Subject: Final Rule: Temp. tol. ex. from a NOF for a permanent exemption

Driss, here is a note from OGC regarding a situation sim. to what we discussed this a.m. Do you think we could do this for MCP?

Sheryl

---- Forwarded by Sheryl Reilly/DC/USEPA/US on 06/11/2001 04:34 PM ----



Suzanne Krolikowski

05/18/2001 03:14 PM

To: Sheryl Reilly/DC/USEPA/US@EPA

cc: Carol Frazer/DC/USEPA/US@EPA

Subject: Re: LPE Final Rule?

Attorney-Client Advice Privileged and Confidential Do Not Disclose

Sheryl:

Suzanne Krolikowski (202) 564-5632 EPA's Office of General Counsel

Sheryl Reilly

**Sheryl Reilly** 05/18/2001 08:06 To: Suzanne Krolikowski/DC/USEPA/US@EPA

cc: Carol Frazer/DC/USEPA/US@EPA

Subject: LPE Final Rule?

---- Forwarded by Sheryl Reilly/DC/USEPA/US on 05/18/2001 08:03 AM -----

**Carol Frazer** 

To: Shery! Reilly/DC/USEPA/US@EPA

05/17/2001 05:01 PM

Subject: LPE Final Rule?

Sheryl,



Carol



Suzanne Krolikowski 04/25/01 05:20 PM To: Mike Mendelsohn/DC/USEPA/US@EPA

cc: Driss Benmhend/DC/USEPA/US@EPA, Janet

Andersen/DC/USEPA/US@EPA, Roger Gardner/DC/USEPA/US@EPA,

Russell Jones/DC/USEPA/US@EPA, Sheryl

Reilly/DC/USEPA/US@EPA

Subject: Re: REVISED VERSION: Question about tolerance exemption

Attorney-Client Advice Do Not Disclose Suzanne Krolikowski

Suzanne Krolikowski (202) 564-5632 EPA's Office of General Counsel

Mike Mendelsohn



Mike Mendelsohn 04/20/01 07:21 AM To: Suzanne Krolikowski/DC/USEPA/US@EPA

cc: Driss Benmhend/DC/USEPA/US@EPA, Janet

Andersen/DC/USEPA/US@EPA, Roger Gardner/DC/USEPA/US@EPA, Russell Jones/DC/USEPA/US@EPA, Sheryl

Reilly/DC/USEPA/US@EPA

Subject: Re: REVISED VERSION: Question about tolerance exemption

Suzanne,

Mike

Suzanne Krolikowski



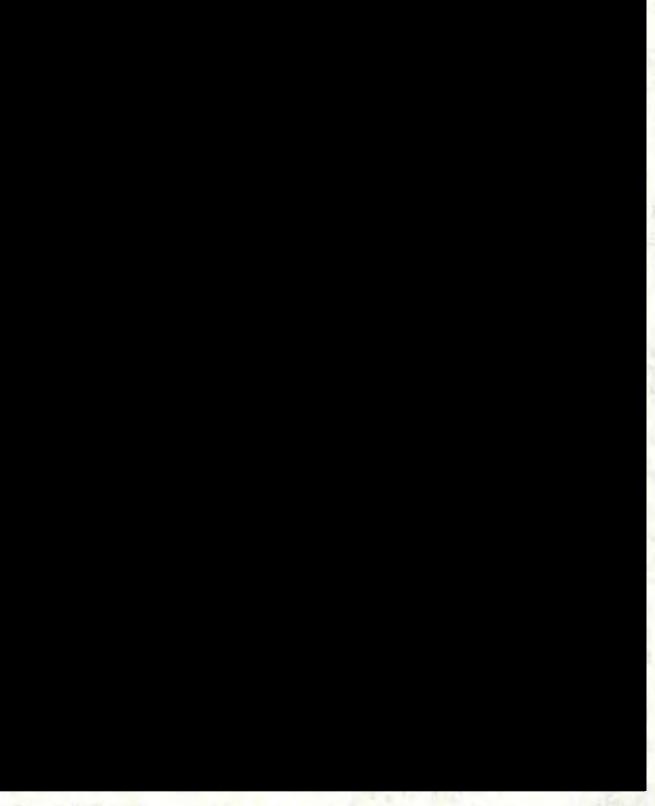
Suzanne Krollkowski 04/19/2001 07:46 PM To: Sheryl Reilly/DC/USEPA/US@EPA

cc: Driss Benmhend/DC/USEPA/US@EPA, Janet Andersen/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Roger

Gardner/DC/USEPA/US@EPA, Russell Jones/DC/USEPA/US@EPA

Subject: Re: REVISED VERSION: Question about tolerance exemption

Attomey-Client Advice Do Not Disclose



Suzanne Krolikowski (202) 564-5632

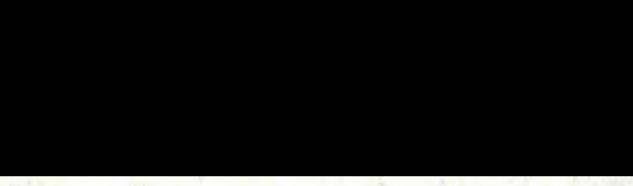
### **EPA's Office of General Counsel**

Sheryl Reilly



Sheryl Reilly 04/19/2001 09:40 AM To: Suzanne Krolikowski/DC/USEPA/US@EPA
cc: Driss Benmhend/DC/USEPA/US@EPA, Janet
Andersen/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA, Roger
Gardner/DC/USEPA/US@EPA, Russell Jones/DC/USEPA/US@EPA

Subject: Re: REVISED VERSION: Question about tolerance exemption



Thanks, Sheryl

OCT 2.2 2001 Attacked You Will Find	the Index of Documents	Submitted Under I	Docket # 305/4	
Pesticide	Product, R	egistiate	in applicati	un
			<u> </u>	

\*When Comments are Received, A Copy of the Comments Will be Enclosed.

Contact the Docket Staff if There are any Questions: (703) 305-5805

\*Comments Enclosed: (Yes) (No)

## Pesticide Product, Registration Applications OPP #30514

NUM	DATE	LNAME	AFFIL	TITLE	PAGES	DOC TYPE
0001	09/19/01	Brenmhend/Rey nolds	EPA	Pesticide Product Registration Application (FR Notice)	4	A
0002	03/28/01	Alphin	Valent	Florbac Lurry Biological Application for Registration	12	A
0003	03/28/01	Wang	Valent	Physical and Chemical Properties of VBC-60008, MRID #453756-01 ("C" Document - See Docket Staff)	25	С
0004	05/09/96	Nair	Valent	HPLC Assay for B-Toxin oin Florbac Strain NB200 Technical Powder, MRID #453756-02 ("C" Document - See Docket Staff)	12	С
0005	05/08/95	Sietske de Noer	Novo Nordisk	Florbac Tech Batch BEB 003 Intratracheal Toxicity MRID #453756-03 ("C" Documents - See Docket Staff)	85	С
0006	06/24/94	Harde	Novo Nordisk	Bt susp. aizawai - Acute Oral Toxicity/Pathoge nicity Study in Rats Dosed Florbac Tech, MRID #453756-04 ("C" Document - See Docket Staff)	42	С

. .

## Pesticide Product, Registration Applications OPP #30514

NUM	DATE	LNAME	AFFIL	TITLE	PAGES	DOC TYPE
0007	06/06/94	Jacobsen	Scantox	Florbac Tech - Acute Dermal Toxicity in the Rat, MRID #453756-05 ("C" Document - See Docket Staff)	13	С
0008	08/16/95	Harde	Novo Nordisk	BT subs. aizawai - Acute Intravenous Toxicity /Pathogenicity Study in Rats Dosed Florbac Tech, MRID #453756-06 ("C" Document - See Docket Staff)	41	С
0009	03/08/95	Sietske de Boer	Novo Nordisk	Florbac Tech Batch BEB 0035 - Primary Skin Irritation Skin Rabbits, MRID #453756-07 ("C" Document - See Docket Staff)	11	С
0010	01/13/95	Sietske de Boer	Novo Nordisk	Florbac Tech, Batch BEB 0035 Eye Irritation in Rabbits, MRID #453756-08 ("C" Document - See Docket Staff)	14	С
0011	03/21/95	Campbell	Wildlife International	Florbac Tech: An Avian Oral Pathogenicity and Toxicity Study in the Northern Bonwhite, MRID #453756-09 ("C" Document - See Docket	41	С

Staff)

# Pesticide Product, Registration Applications OPP #30514

NUM	DATE	LNAME	AFFIL	TITLE	PAGES	DOC TYPE
0012	03/21/95	Campbell	Wildlife International	Florbac Tech: An Avian Oral Pathogenicity and Toxicity Study in the Mallard, MRID #453756-10 ("C" Document - See Docket Staff)	44	С
0013	09/08/04	Memmert	RCC Umweltchemie GmbH & Co	Chronic Toxicity and Pathogenicity of Florbac Tech MRID #453756-11 ("C" Documents - See Docket Staff)	40	С
0014	09/08/94	Memmert	RCC Umweltchemie GmbH & Co	Influuence pf Florbac Tech. on Survival and Reproduction of Daphnia Magna in a Semistatic Test, MRID #453756-12 ("C" Document - See Docket Staff)	32	С
0015	06/02/95	Palmer	Wildlife International	Dietary Pathogenicity and Toxicity Study w/Parasitic Hymenoptera, MRID #453756-13 ("C" Document- See Docket Staff)	28	С
0016	06/02/95	Palmer	Wildlife International	Florbac Tech: Dietary Pathogenicity and Toxicity Study w/the Ladybird Beetle, MRID	31	С

#453756-14 ("C" Document - See Docket Staff)

. .

. . .

# Pesticide Product, Registration Applications OPP #30514

NUM	DATE	LNAME	AFFIL	TITLE	PAGES	DOC TYPE
0017	06/02/95	Palmer	Wildlife International	Florbac Tech: Dietary Pathogenicity and Toxicity Study w/Green Lacewing Larvae, MRID #453756-15 ("C" Document - See Docket Staff)	29	С
0018	06/02/95	Palmer	Wildlife International	Florbac Tech: Dietary PAthogenicity and Toxicity Study w/the Honey Bee, MRID #453756-16 ("C" Document - See Docket Staff)	30	С
0019	06/25/01	Tinsworth	Novigen	Registration Application for a New Active Ingredient Amplify Sprout InhibitorM RID #454388-00 (C"C Document - See Docket Staff)		С
0020	02/12/01	San	BioReliance	InVitro Mammalian Cell Gene Mutation Test, MRID #454388-01 ("C" Document - See Docket Staff)	35	С
0021	06/25/01	Polakoff	Platte Chemical Co.	Summary Report: Amplify (2,6-DIPN) 1999-2000 Experimental Use Permit, MRID #454388-02 ("C Document -		С

Page No. 5 10/22/01

\*\*\* Total \*\*\*

. . .

# Pesticide Product, Registration Applications OPP #30514

NUM	DATE	LNAME	AFFIL	TITLE	PAGES	DOC TYPE
0022	06/15/01	Novigen Sciences, Inc	Novigen	Amplify Sprout Inhibitor TechnicalMR ID #454388-03 ("C" Document - See Docket Staff)	6	С
0023	06/25/01	Polakoff	Novigen Sciences	Chronic and Acute Dietary Risk Assessment: 2,6-DIPN on Potatoes, MRID #454388-01 ("C" Document -See Docket Staff)	84	С
0024	10/12/01	Jensen	Washington State Potato Commission	Pesticide Product Registration Application (FR Notice)	2	A
0025	10/19/01	Olberding	National Potato Council	Comments Re: Pesticide Product Registration Application DIPN (Amplify)	3	A

675

PESTICIDE REGISTRATION ACTION TRACKING (PRAT) -- Action Codes

Printed 1/20/95 Revised 05/10/94 [FB]

(previous rev.10/93)

- A. Registration (Registration Division use only)
- 010 New Chemical Screening 011 - Resubmission
- 015 First Food Use Screening 016 - Resubmission
- 100 Application for Registration New Chemical Food or Feed 101 - Resubmission
- 110 Application for Registration AmD New Chemical Non-Food or Non-Feed Use\*\*
  111 Resubmission
- 115 Application for Registration New Chemical Non-Food or Non-Feed Use
  116 Resubmission
- 117 Proposed Test Protocol New Chemical 118 - Resubmission
- 130 Application for Registration New Biological Food or Feed Use
  131 Resubmission
- 145 Application for Registration New Biological Non-Food or Non-Feed Use
  146 Resubmission
- 152 Proposed Test Protocol New Biological 153 - Resubmission
- 157 Data Waiver Request New Biological 158 - Resubmission
- \*160 Application for Registration Routine "Me-Too" (Use 165 if HED/EFED review required)
  \*161 Resubmission
- 163 Data Waiver Request Old Chemical 164 - Resubmission
- 165 Application for Registration Old Chemical (Minor changes, i.e, substantial change in percentage of active ingredients, inerts, etc.) Requires HED/EFED review.

  166 Resubmission
- \*PRAT Action Codes subject to FIFRA'88 45/90 day time requirements.
  \*\*Action Codes subject to FQPA timeframe goals for antimicrobials.

- 167 Nitrosamine Data Old Chemical 168 - Resubmission
- 170 Application for Registration Old Chemical "Me-Too" with an Additional Use (Use 175 if HED/EFED review required) 171 - Resubmission
- 172 Application for Registration AmD Old Chemical -New Product - Routine "Me-Too" \*\* 173 - Resubmission
- 175 Application for Registration Old Chemical New Use -Non-Food or Non-Feed - Requires HED/EFED review. 176 - Resubmission 177 - Proposed Test Protocol - Old Chemical 178 - Resubmission
- 180 Application for Registration Old Chemical First New Food or Feed Use 181 - Resubmission
- 184 Application for Registration AmD New Uses New Product -Old Chemical - New Non-food or Non-feed Use\*\* 185 - Resubmission
- 186 Application for Registration AmD Old Chemical New Product - Old Chemical Minor Change\*\* 187 - Resubmission
- 188 Application for Registration AmD Old Chemical New Product - Old Chemical "Me-Too" W/Additional Use\*\* 189 - Resubmission
- 192 Proposed Test Protocol New Use 193 - Resubmission
- 194 Action Init. by Agency Add'l. Request 195 - Resubmission
- Tolerance Petition/Inert Ingredient Clearance (Registration Division use only)
- 200 "E" Petition Minor Use (IR-4/State) 201 - Resubmission 202 - Amendment 203 - Resubmission/Amendment
- 205 "E" Petition (not IR-4) Inerts (establish or exemption) 206 - Resubmission

- 210 "E" Petition (not IR-4) Minor Use 211 - Resubmission
- 212 "E" Petition (not IR-4) Minor Use Amendment 213 - Resubmission
- 220 "E" Petition Imports Only 221 - Resubmission
- 222 "E" Petition Imports Only Amendment 223 - Resubmission
- 230 "F" Petition Raw Agricultural Commodity 231 - Resubmission
- 232 Amendment "F" Petition-Raw Agri.Comm-Substantive (With Data)
  233 Resubmission w/ Data
- 234 Amendment "F" Petition-Raw Agri.Comm-Non-Subst (No Data)
  235 Resubmission No Data
- 240 "G" Petition Temporary Tolerance 241 - Resubmission
- 242 Amendment "G" Petition Temporary Tolerance 243 - Resubmission
- 246 Renewal/Extension Request 247 Resubmission
- 250 "H" Petition Food Additive 251 - Resubmission
- 252 Amendment "H" Petition Food Additive 253 - Resubmission
- 260 "H" Petition Temporary Food Additive Petition 261 - Resubmission
- 262 Amendment "H" Petition Temporary Food Additive Petition 263 Resubmission
- 266 Renewal/Extension "H" Petition Temporary Food Additive 267 Resubmission
- 268 General Correspondence Tolerances 269 - Resubmission
- 270 Inert Ingredient Clearance Request 271 - Resubmission
- 272 Inerts DCI Submission (if moved from list 2 to 1)

273 - Resubmission

- 274 Inert Data Waiver Request 275 - Resubmission
- C. Amendments (Registration Division only)
- \*300- Amendment Label Revision Administrative (No data required, name change, etc.)
  \*301 Resubmission
- \* PRAT Action Codes subject to the FIFRA'88 45/90 day time requirements
- 302 Amendment AmD Administrative Label Revision No Data Required\*\* 303 - Resubmission
- 305 Amendment Technical Label Revision Data Required (i.e., change in toxicity category, etc.) Use 320 if HED/EFED review required.

  306 Resubmission
- 307 Amendment AmD Technical Label Revision Data Required\*\* 308- Resubmission
- \*310 Amendment Technical Added "Me-Too" Use (Use 325 if HED/EFED review required)

  \*311 Resubmission
- 312 Amendment AmD Technical Added "Me-Too" Use\*\*
  313 Resubmission
- 315 Amendment New Use Non-Food or Non-Feed 316 - Resubmission
- 317 Amendment AmD New Uses New Non-Food or New Non-Feed
  Use\*\*
  318 Resubmission
- 320 Amendment Label revision Data required Requires
  HED/EFED review.
  321 Resubmission
- 322 Amendment AmD Label Revision Data Required Requires Scientific Review\*\* 323 - Resubmission

- 325 Amendment Added "Me-too" use Data required requires
  HED/EFED review.
  326 Resubmission
- 327 Amendment AmD Added "Me-Too" Use Data Required Requires Scientific Review\*\*
  328 Resubmission
- 330 Amendment Technical New Use Food or Feed (Use 370/371 if first food or feed use for chemical)
  331 Resubmission
- 332 Amendment AmD Notification\*\*
  333 Resubmission
- 335 Use Deletions 336 - Resubmission
- 341 Amendment AmD Formula Change Unregistered Source of Active Ingredient\*\*
  342- Resubmission
- \*345 Amendment Technical Formula Change (Use 347 if HED/EFED review required.

  \*346 Resubmission
- 347 Amendment Formula Change Unregistered source of the active ingredient. (Requires HED/EFED review)
  348 Resubmission
- 350 General Correspondence Registration 351 Resubmission
- 352 Proposed Test Protocol Amendments 353 - Resubmission
- 354 Lab Audit Program Data Review 355 Resubmission
- 356 Label Improvement Program Notification 357 - Resubmission
- 358 Classification by Regulation (Agency Initiated)
  359 Resubmission
- \* PRAT Action Codes subject to the FIFRA'88 45/90 day time reqs.
- 360 Action Initiated by Agency Registration & Amendment 361 - Resubmission

- 362 Amendment AmD Formula Change\*\*
  363 Resubmission
- 370 Amendment New Use First Food or Feed Use for Chemical 371 Resubmission
- 383 Amendment AmD Inert Label Warning Statement\*\*
  384 Resubmission
- 385 Amendment Special Packaging (Sect. 162.16) 386 - Resubmission
- 387 Amendment AmD Special Packaging\*\*
  388 Resubmission
- 390 Amendment Inert Substitution 391 - Resubmission
- 395 Amendment Inert Label Warning Statement 396 - Resubmission
- 397 Amendment AmD Minor Formulaton Change for End Use Product\*\* 398 - Resubmission
- D. Miscellaneous (Registration Division use only)
- 400 Miscellaneous Data (data not requested). Does not include Adverse Data submissions (see A Code 405) 401 - Resubmission
- 405 Adverse Data [Section 6(a)(2)] submission. 406 - Resubmission
- 410 Data Call-in [FIFRA Section 3(c)(2)(B)] 411 - Resubmission
- 445 Exemption Request Child Resistant Packaging (Sect. 162.16)
  446 Resubmission
- 455 Enforcement Case Reviews

### Worker Protection Standards Amendments

- 460 Request for Cancellation 461 Resubmission
- 462 Use deletion amendment (out of scope)
  463 Resubmission

- 464 Standard Compliance Label Amendment 465 Resubmission
- 466 Non-Standard Compliance Label Amendment 467 Resubmission
- 468 Non-Standard Label Amenment plus other action 469 Resubmission

- E. Emergency Exemptions/Conditional Registration/Special Local Needs (Registration Division use only)
- 500 Section 18 Specific Exemption New Chemical Food or Feed Use.
  - 501 Resubmission
  - 502 Final Report
  - 503 Amendment
- 505 Section 18 Specific Exemption New Chemical Non-Food or Non-Feed Use.
  - 506 Resubmission
  - 507 Final Report
  - 508 Amendment
- 510 Section 18 Specific Exemption Old Chemical Food or Feed Use
  - 511 Resubmission
  - 512 Final Report
  - 513 Amendment
- 515 Section 18 Specific Exemption Old Chemical Non-Food or Non-Feed Use.
  - 516 Resubmission
  - 517 Final Report
  - 518 Amendment
- 520 Section 18 Quarantine New Chemical Food or Feed Use.
  - 521 Resubmission
  - 522 Final Report
  - 523 Amendment
- 525 Section 18 Quarantine New Chemical Non-Food or Non-Feed Use.
  - 526 Resubmission
  - 527 Final Report
  - 528 Amendment
- 530 Section 18 Quarantine Old Chemical Food or Feed Use.
  - 531 Resubmission
  - 532 Submission Final Report
  - 533 Amendment
- 535 Section 18 Quarantine Old Chemical Non-Food or Non-Feed Use.
  - 536 Resubmission
  - 537 Final Report
  - 538 Amendment

- 550 Section 18 Crisis Exemption Old Chemical Food or Feed Use.
  - 551 Resubmission
  - 552 Final Report
  - 553 Amendment
- 555 Section 18 Crisis Exemption Old Chemical Non-Food or Non-Feed Use.
  - 556 Resubmission
  - 557 Final Report
  - 558 Amendment
- 560 Section 18 Public Health Exemption New Chemical
  - 561 Resubmission
  - 562 Final Report
  - 563 Amendment
- 565 Section 18 Public Health Exemption Old Chemical
  - 566 Resubmission
  - 567 Final Report
  - 568 Amendment
- 569 General Correspondence Emergency Exemption
- 570 Conditional Registration Follow-up Data Requiring RD Review
  571 Resubmission
- 575 Conditional Registration Follow-up Data Requiring
  HED/EFED Review
  576 Resubmission
- 580 Special Local Need 24(c) Application Food or Feed Use.
  - 581 Resubmission
  - 582 Amendment
  - 583 Resubmission
- 585 Special Local Need 24(c) Application Non-Food or Non-Feed Use.
  - 586 Resubmission
  - 587 Amendment
  - 588 Resubmission
- F. Reregistration (Active Ingredient Reregistration)
- 606 Data Package Review (except voluntary cancellation, use 900) 607 - Phase 5 Resubmission
- 610 Time Extension Request (submitted outside of phase 2 to 5 response)
  611 Resubmission

- 614 Data Waiver Request Submission (including extensions of existing data waiver request and new data waiver request)
  615 Waiver Request Resubmit
- 618 Initiate LUIS Report For RED Development
- 619 Initiate RED Product Specific For RED Development
- 620 3(c)2(B) 90 Day Response (including data requirement and guideline revisions)
  621 3(c)2(B) Resubmission
- 623 Initiate RED Chapter For RED Development
- 625 6(a)(2) Reregistration/Special Review 626 - 6(a)(2) Resubmission
- 627 Generic Data Submission (required but submitted outside phase 2 to 5 response)
  628 Generic Data Resubmission
- 629 General Correspondence Reregistration
- 635 Proposed Test Protocol Submission 636 - Protocol Resubmission
- 645 Tolerance Revocation/Amendment

#### Product Reregistration

- 650 Data Waiver Request Reregistration 651 - Resubmission
- 655 Formulation Data and Labeling Submission Reregistration 656 Resubmission
- 660 Generic Data Submission Reregistration 661 - Resubmission
- 662 Issuance of Reregistration Eligibility Document (RED) 663 Resubmission
- 665 Protocol Review Reregistration (Reg. Div. use)
  666 Resubmission
- 667 Expedited Labeling Response Reregistration 668 Resubmission
- 670 90 day Response to RED Data Call-In 671 Resubmission

- 674 8 Month Response to RED Application for Reregistration Product Specific Data & Labeling
  675 Resubmission
- 676 Time Extension Request 677 - Resubmission
- 680 IR-4 Data (Minor Use) Reregistration 681 Resubmission
- 690 General Correspondence (RD only)
- 697 Congressional Inquiry
- G. Experimental Use Permits (Registration Division use only)
- 700 EUP New Chemical Non-Food or Non-Feed Use 701 - Resubmission
- 704 Amendment EUP New Chemical Non-Food or Non-Feed Use 705 Resubmission
- 706 Extension/Renewal EUP New Chemical-Non-Food or Non-Feed Use 707 Resubmission
- 709 Final Report EUP New Chemical Non-Food or Non-Feed Use
- 710 EUP New Chemical Food or Feed Use 711 - Resubmission
- 714 Amendment EUP New Chemical Food or Feed Use 715 - Resubmission
- 716 Extension or Renewal EUP New Chemical Food or Feed Use 717 Resubmission
- 719 Final Report EUP New Chemical Food or Feed Use
- 720 EUP New Chemical Biological Non-Food or Non-Feed Use 721 - Resubmission
- 724 Amendment EUP New Chemical Biological Non-Food or Non-Feed Use 725 - Resubmission
- 726 Extension or Renewal Request EUP New Chemical -Biological - Non-Food or Non-Feed Use 727 - Resubmission
- 729 Final Report EUP New Chemical Biological Non-Food or Non-Feed Use

- 730 EUP New Chemical Biological Food or Feed Use 731 - Resubmission
- 734 Amendment EUP New Chemical Biological Food or Feed Use 735 - Resubmission
- 736 Extension or Renewal Request EUP New Chemical Biological Food or Feed Use
  737 Resubmission
- 739 Final Report EUP New Chemical/Biological-Food or Feed Use
- 740 EUP Old Chemical Non-Food or Non-Feed Use 741 - Resubmission
- 744 Amendment EUP Old Chemical Non-Food or Non-Feed Use 745 - Resubmission
- 746 Extension or Renewal Request EUP Old Chemical Non-Food or Non-Feed Use 747 Resubmission
- 749 Final Report EUP Old Chemical Non-Food or Non-Feed Use
- 750 EUP Old Chemical Food or Feed Use 751 - Resubmission
- 754 Amendment EUP Old Chemical Food or Feed Use 755 - Resubmission
- 756 Extension or Renewal Request EUP Old Chemical Food or Feed Use
  757 Resubmission
- 759 Final Report EUP Old Chemical Food or Feed Use
- 785 Protocol Review Request EUP 786 - Resubmission
- 790 Novel Microbial Pesticides (Notification)
  791 Resubmission
- H. Special Review (Special Review and Reregistration Division use only)
- 810 Time Extension Special Review
- 811 Risk Assessment Special Review
- 812 Benefit Assessment Special Review

Revised 10/18/93

- 813 Exposure Assessment Special Review
- 814 Data Waiver Request Special Review 815 - Resubmission
- 820 Special Review DCI Submission 821 - Resubmission
- 825 6(A)(2) Potential Adverse Effects Special Review 826 Resubmission
- 835 Proposed Test Protocol Special Review 836 - Resubmission
- 845 Review of Public Comments Special Review
- 846 Supplemental Submission
- 860 SRB Other
- 880 Tolerance Revocation

- I. Cancellation/Suspension
- 900 Cancellation Voluntary (Company request). 901 - Resubmission
- 905 Cancellation Section 6(e). 906 - Resubmission
- 910 Cancellation Special Review 911 - Resubmission
- 915 Cancellation Undeliverable 916 - Resubmission
- 925 Suspension 926 - Resubmission
- 927 Suspension (Reregistration) 928 - Resubmission
- 929 Suspension (Special Review) 930 - Resubmission
- 931 Suspension (Inert Ingredient) 932 - Resubmission
- 935 Cancellation Inert Ingredient 936 - Resubmission

Revised 10/18/93

945 - Cancellation - Other
(i.e. phase 2 & 3 noncompliance; reregistration fee; maintenance fee)
946 - Resubmission



Suzanne Krolikowski 04/19/01 07:46 PM

To: Sheryl Reilly/DC/USEPA/US@EPA
cc: Driss Benmhend/DC/USEPA/US@EPA, Janet
Andersen/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Roger Gardner/DC/USEPA/US@EPA, Russell

Jones/DC/USEPA/US@EPA

Subject: Re: REVISED VERSION: Question about tolerance exemption

Attorney-Client Advice Do Not Disclose





Suzanne Krolikowski (202) 564-5632 EPA's Office of General Counsel

Sheryl Reilly



**Sheryl Reilly** 04/19/2001 09:40 AM

To: Suzanne Krolikowski/DC/USEPA/US@EPA
cc: Driss Benmhend/DC/USEPA/US@EPA, Janet
Andersen/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA, Roger
Gardner/DC/USEPA/US@EPA, Russell
Jones/DC/USEPA/US@EPA

Subject: Re: REVISED VERSION: Question about tolerance exemption



Suzanne Krolikowski 04/18/01 09:49 AM To: Janet Andersen/DC/USEPA/US@EPA
cc: Driss Benmhend/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA, Roger
Gardner/DC/USEPA/US@EPA, Russell

Jones/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA

Subject: Re: Question about tolerance exemption

Attorney-Client Advice Do Not Disclose

Janet Andersen

**Janet Andersen** 

04/18/2001 07:08 AM

To: Suzanne Krolikowski/DC/USEPA/US@EPA
cc: Driss Benmhend/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA, Roger
Gardner/DC/USEPA/US@EPA, Russell

Jones/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA

Subject: Re: Question about tolerance exemption

Suzanne Krolikowski



Suzanne Krolikowski 04/17/01 06:48 PM To: Janet Andersen/DC/USEPA/US@EPA

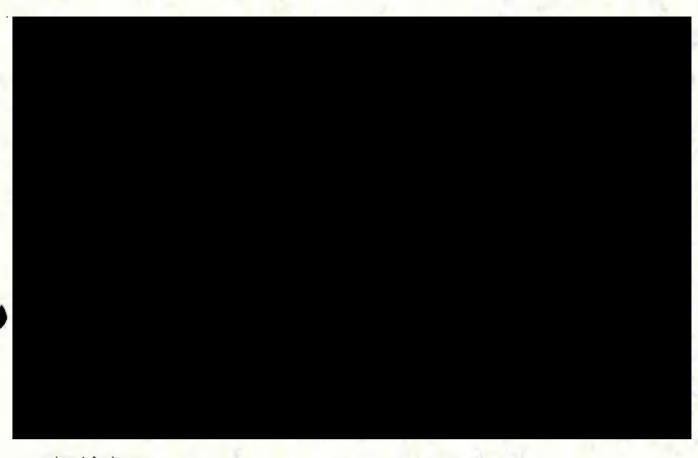
cc: Driss Benmhend/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Roger Gardner/DC/USEPA/US@EPA, Russell

Jones/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA

Subject: Re: Question about tolerance exemption

Attorney-Client Advice Do Not Disclose

Janet and Sheryl,



Janet Andersen

**Janet Andersen** 

04/17/2001 04:58 PM

To: Sheryl Reilly/DC/USEPA/US@EPA

cc: Driss Benmhend/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Roger Gardner/DC/USEPA/US@EPA, Russell Jones/DC/USEPA/US@EPA, Suzanne Krolikowski/DC/USEPA/US@EPA

Subject: Re: Question about tolerance exemption

Sheryl Reilly



**Sheryl Reilly** 04/17/01 02:30 PM

To: Suzanne Krolikowski/DC/USEPA/US@EPA
cc: Driss Benmhend/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA, Roger
Gardner/DC/USEPA/US@EPA, Russell

Jones/DC/USEPA/US@EPA, (bcc: Janet Andersen/DC/USEPA/US)

Subject: Question about tolerance exemption

Hi, Suzanne,





Stephen L Longacre@RohmHaas.Com (Stephen L Longacre) on 03/16/2001 09:33:42 AM

To: Driss Benmhend/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA

cc:

Subject: Preliminary 14C-1-MCP Apple Residue Results

Driss and Sheryl,

In my response to the Agency's Science Review of our petition for an exemption from the requirement of 1-MCP residues on food commodities (OF 06144), I indicated that we have completed our difficult methods development for measuring very low levels of a volatile active ingredient and have initiated our definitive residue studies with 14C-1-MCP in apples. Our initial definitive trial has been completed, and preliminary residue results from this trial are attached ('residuel.doc'). These data are for your use in your ongoing discussions regarding my recent requests for a timely granting of an exemption from tolerance for 1-MCP on food commodities, and for conditional registration for indoor use of EthylBloc Technology (0.14% 1-MCP) on harvested fruits and vegetables.

Negligible concentrations of residues were detected (2-4 parts per billion)

in the apples treated with 1.2 ppm (1200 ppb) 1-MCP for 24 hr. The small amount of detected radioactivity was reasonably distributed among all apples in the treatment chamber. These preliminary results support our petition indicating that any potential residues would be negligible and below the theoretical maximum amount of 9 ppb which assumes that ALL of

the

1-MCP in the treatment room ended up in/on the apples. These residue concentrations are below reasonable non-radiolabeled analytical detection limits.

The margins of safety for dietary exposure assuming the worst case that ALL consumed food contains 9 ppb (0.009 ppm) 1-MCP residues are huge (thousands-fold margin of safety). Dietary risks assessments are indicated in my response to Valent Biosciences' comments that I submitted to the Agency 19Dec00 (SLL-00-303), and will be contained in a document that I will submit to the Agency later this month.

Again, I am available at any time to dicuss our request for a timely granting of an exemption from tolerance for 1-MCP on food commodities and a conditional registration for EthylBloc technology indoor post-harvest food use.

Regards,

Steve Longacre
AgroFresh, Inc./Rohm and Haas Company
T: 215-592-3581

BPPI	PRAT	ACTION	CODING	FORM	
ROHM PM 90: Janet Ande	ersen HAA	S RE	VIEWER: PAR	of medded	_
EPA REG./FILE SY	MBOL 112	97-1	Amer	dment	
ACTION CODE 3	05		4.5		
(NEW a.i./EUPs/To	lerances: Yes_		100		
SUBMISSION BAR	CODE 559	4574			
DATE ON APPLICA	ATION 4/4	1/6/			
EPA RECEIVED DA		•			
PM RECEIVED DA	TE 4/19	101			
ASSIGNED IN PRA					
COMPLETED BY:_	T. Bett	eA DATE:	5/1/01		
<b>***********</b>	200000000000000000000000000000000000000		methyl - (701 , 80) cooccessessesses	(921) (CA Inde	Seess
FINAL ACT	ION	T. E.		7	
Response Code	-2:				
Response Date:					1
MOS:	(1) Cite-All				
	(4) Not Applica	able			
	(8) Selective				
CRP:	Y'es	No			
Restricted Use:	Yes	No			
Manufacturing Use;	Y es	N)			
Exclusive Use:	25	X			225

FRONT END PROCESSING APPLICATIO	N INFORMATION CHECK LIST
РМ_9/	
EPA COMPANT NUMBER 7/297 -	_/
EPA REGISTRATION NUMBER STATUS (FOR AMENDMENTS)	ACTIVECANCELLED NOT IN REFS
"ME-TOO" CITED PRODUCT STATUS	ACTIVE CANCELLED  NOT IN REFS
OPP# 284868 DATE	4-18-01

## AMENDMENT

# APPLICATION FOR AMDENDMENT

WITH DATA		WITHOUT D	<u>ATA</u>
INIT.	DATE	INIT.	DATA
FEU		FEU Yew	:4-18-01
SIG. (DATA)		PM 9/	
PM			
	OPP # 2	14868	



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

04/18/2001

AMY PLATO ROBERTS
TECHNOLOGY SCIENCES GROUP, INC.
1101 17TH STREET, NW, SUITE 500
WASHINGTON DC 20036

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PRODUCT NAME: ETHYLBLOC

COMPANY NAME: TECHNOLOGY SCIENCES GROUP, INC

OPP IDENTIFICATION NUMBER: 284868
EPA REGISTRATION NUMBER: 71297-1
EPA RECEIPT DATE: 04/06/2001

SUBJECT: RECEIPT OF AMENDMENT

#### DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Sheryl Reilly, Product Manager 91, at (703) 308-8269.

Sincerely,

- Mrice

Front End Processing Staff
Information Services Branch
Program Management and Support Division

<b>⊕EPA</b>	United States Environmental Protection Washington, DC 204		X Amend Other	284868
	Application	for Pesticide - Se	ection I	
1. Company/Product Number		2. EPA Product f		Proposed Classification
71297-1-32258		Driss Benmhe	end	
4. Company/Product (Name	e)	PM#		None Restricted
EthylBloc®		91		None Restricted
5. Name and Address of Ap AgroFresh, Inc./ Rohm a 100 Independence Mall Philadelphia, PA 19106	nd Haas Company West	(b)(l), my product to: EPA Reg. No	is similar or ident	nce with FIFRA Section 3(c)(3) ical in composition and labeling
		Section - II		
Notification - Explain b  Explanation: Use additiona	al page(s) if necessary. (For Sec ray solution application of EthylB	Other - Extition I and Section II.): loc onto potted plants, b	Application. plain below.	nd foliage plants in enclosed areas,
		Section - III		
1. Material This Product V Child-Resistant Packaging Yes* No  * Certification must be submitted	Unit Packaging Yes No  If "Yes" No. per Unit Packaging wgt. containe		per ntainer	of Container  Metal  Plastic  Glass  Paper  Other (Specify)
Location of Net Contents  Label C	Information 4. Size ontainer	(s) Retail Container	On	of Label Directions Label Labeling accompanying product
6. Manner in Which Label is	s Affixed to Product	Lithograph Paper glued Stenciled	Other	
		Section - IV	-	
1. Contact Point (Complete	items directly below for identifica		ontacted, if necess	sary, to process this application.)
Name	Title	A Desistantia - Marro		hone No. (Include Area Code)
	Certification ave made on this form and all attachingly false or misleading statement ma		urate and complete.	6. Date Application Received

**Product Registration Manager** 

April 4, 2001

5. Date

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

Typed Name

Stephen L. Longacre, Ph.D.

White - EPA File Copy (original)

Yellow - Applicant Copy

Form	Approv	ed	OMR	Mo	2070	-0060
	APPIO	ou.	CIAID	100.	2010	VVVV



# United States

Registration
Amendment
Other

**OPP Identifier Number** 

Washington, DC		Amendmen Other	284868
Applica	ation for Pesticide - Sec	ction i	
1. Company/Product Number	2. EPA Product Ma	nager	3. Proposed Classification
4. Company/Product (Name)	PM#		None Restricted
5. Name and Address of Applicant (Include ZIP Code)			with FIFRA Section 3(c)(3) n composition and labeling
Check if this is a new address	Product Name	1	
	Section - II	7	
Amendment - Explain below.  Resubmission in response to Agency letter dated  Notification - Explain below.	Agency le "Me Too"	ed labels in response to tter dated Application.	
Explanation: Use additional page(s) If necessary. (For se			
	Section - III		
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging  Yes*  No  Certification must be submitted  Unit Packaging  Yes  No  If "Yes" Unit Packaging wgt.	ner Package wgt contain	Gle	stal
3. Location of Net Contents Information 4. Size(s)	) Retail Container	5. Location of Label Di	rections
Label Container		On Label	coompanying product
<u> </u>	thograph Oth	1	ocompanying product
P. Manner in William Label is Affixed to Poddet	thogreph Oth aper glued tenciled	let /	
/	Section - IV		
1. Contact Point (Complete items directly below for identific		d W necessary to proper	e this application I
Name	Title		phone No. (Include Area Code)
Name	nu•	) leie	phone No. (include Area Code)
Certify that the statements I have made on this form I acknowledge that any knowingly false or misleading both under applicable law.			8. Date Application Received (Stamped)
2. Signature	3. Title		
4. Typed Name	5. Date		

### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT MOTICE: Public reporting burden for this collection of information is estimated to everage 0.85 hour per response, including time for reviewing instructions, asserching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send completing regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)]:
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of eny data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Deta - Date submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please reed the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, raregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION | - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been essigned by EPA. This number may have been essigned to you as a
  basic registrent, a distributor, or as an astablishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are setting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not realding in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other posticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for raregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter dete if appropriete. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a saparate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be merketed,
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product lebel is attached to retail container.

SECTION IV (Contect Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

Please And instructions on re	everse before completi	ina form.	-	Form Approved	I. OMB No. 20	70-0060	Contain .
O EDA	Ur Environmental	nited States			Registra Amenda Other	tion	OPP Identifier Number 284868
	1	Application	for Pestic	ide - Section	n I		
1. Company/Product Number			2. EPA	Product Manager		3. Pr	oposed Classification
4. Company/Product (Name)			PM#			7	None Restricted
5. Name and Address of App  Check if this	licent (Include ZIP Cod	ie)	(b)(i), i to: EPA		milar or ident		FIFRA Section 3(c)(3) mposition and labeling
			Section -		7		
Amendment - Explain Resubmission in respo	onse to Agency letter	dated		Final printed lab Agency letter d "Me Too" Appli Other - Explain	eted cetion.	to	
			Section -	<u></u>			
1. Material This Product Will	Be Packaged in:						
Child-Resistant Packaging Yes* No * Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per pontainer	Water Soluble Yes No If "Yes" Package wgt	No. per container	2. Type of	Metal Plastic Glass Paper	Specify)
3. Location of Net Contents	Information ontainer	4. Size(s) Reta	il Container	15. I	Location of Laboration On Laberation		ons opanying product
6. Manner in Which Label is	Affixed to Product	Lithogra Paper g Stencile	ph lued	Other			
	_/		Section -	IV			
1. Contact Point (Complete	items directly below for	or identification	of individual to	be contacted, if n	eclassary, to pr	ocess this	application.)
Name		1	Title			Telephon	e No. (include Area Code)
	ments I have made on by knowingly false or m law.	nisleading state	attachments t				6. Date Application Received (Stamped)

5. Date

4. Typed Name

#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send completing the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any date submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels mey be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storaga in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Date - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reragistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration ections.

- 1. Company/Product Number Insert your Company Number, if one has been essigned by EPA. This number may have been assigned to you as a basic registrent, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for tham in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other posticide products that are currently registered with the EPA. In order for your application to be eligible for expedited raview, you must provide us with the EPA Registration Number and product name of the product you balieve is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

<u>SECTION III</u> (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicete type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.



April 4, 2001

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U. S. Environmental Protection Agency
Mr. Driss Benmhend
Biopesticides & Pollution Prevention Division
Room 266A, Crystal Mall #2
1921Jefferson Davis Highway
Arlington, VA 22202-4501

SLL-01-085

Dear Mr. Benmhend:

Subject: EthylBloc® (EPA Reg. No. 71297-1-32258)

Active Ingredient = 1-Methylcyclopropene (1-MCP)
Label Amendment to Add Spray Solution Application

AgroFresh, Inc., a fully-owned subsidiary of Rohm and Haas Company, requests a label amendment to the currently approved EthylBloc flower/non-food use label to add spray solution application of EthylBloc/1-MCP in enclosed areas, such as greenhouses. Floralife, Inc., our sub-registrant, has conducted studies to demonstrate the usefulness of the spray solution application technique. A small amount of EthylBloc would be added to water (1.5 grams EthylBloc powder per gallon of water) and immediately sprayed onto potted plants, bedding, or nursery and foliage plants. The amount of EthylBloc powder and 1-MCP active ingredient applied via spraying is much less than the corresponding amount of EthylBloc powder and 1-MCP active ingredient that would be applied as a gas treatment for a given amount of plants within a given volume.

Please contact me by phone (215-592-3581), fax (215-592-3414), or email (rstysl@rohmhaas.com) if you have any questions about this label amendment request.

Sincerely,

Stephen L. Longacre, Ph.D.

St Largane

Product Registration Manager

Agricultural Chemicals Registration and Regulatory Affairs Department

cc: Jim Daly (Floralife, Inc.)

Jay Holmdal (Rohm and Haas)

D. Benmhend 04Apr01 Page 2

Administrative materials submitted with this letter (5 copies of label):

EPA Form 8570-1 (OPP Identifier No. 250082);

Draft label for EthylBloc (EPA Reg No. 71297-1-32258; SLL/03Apr01)



February 21, 2001

Document Processing Desk - 6(a)2
Office of Pesticide Programs (H7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

SLL-01-063

Dear Sir or Madam:

Subject: Submission of Information under FIFRA Section 6(2)2

Rohm and Haas Company's fully-owned subsidiary, AgroFresh, Inc. (formerly Biotechnologies for Horticulture, Inc.) is hereby submitting under FIFRA Section 6(a)2 results of a female rat two-week inhalation toxicity study conducted with CAS No. 3100-04-7, the active ingredient in product EPA Registration No. 71297-1.

In the study, CAS No. 3100-04-7 was administered via Inhalation (whole body 6-hour exposure) at 0 ppm, 100 ppm (0.22 mg/L), 300 ppm (0.66 mg/L), or 1000 ppm (2.2 mg/L) to groups of 7 female Crl;CD® BR rats for 9 days over a two-week period. The animals were killed and evaluated for body weight and feed consumption, clinical signs, hematology and clinical chemistry, organ weights, and histopathology.

No effects were observed at 100 ppm (equivalent to 63 mg/kg/day). At 300 ppm, increased extramedullary hematopoiesis (minimal to mild in severity) was observed in the spleen of 4 of 7 animals. At 1000 ppm, minimal decreases (<10% change) in total red blood cells, hemoglobin, and hematocrit were observed along with increased spleen weight and increased extramedullary hematopoiesis (mild to moderate in severity) in the spleen. No treatment-related clinical signs or body weight changes were observed at any dose.

The results of increased extramedullary hematopolesis of the spleen, increased spleen weight, and the decreased hematologic parameters have not been observed previously for CAS No. 3100-04-7, and we are submitting this information to the Agency on this basis.

A final report on this study will be submitted to the Agency later this year when it has been completed.

EPA/6(a)2 21Feb01 Page 2

Please contact me by telephone (215-592-3581), fax (215-592-3414) or e-mail (rstysl@rohmhaes.com) if you have any questions about this letter.

Sincerely,

Stephen L. Longacre, Ph.D.

Product Registration Manager
Agricultural Chemicals Registration
and Regulatory Affairs Department

cc: Mr. Driss Benmhend/EPA 8PPD

#### DRAFT



February 2, 2001

Mr. Driss Benmhend
Biopesticides & Pollution Prevention Division
Office of Pesticide Programs (7511C)
U.S. Environmental Protection Agency
Room 902, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

SLL-01-033

Dear Mr. Benmhend:

Subjects: Major Points and Follow-Up Actions from Our 23Jan01 Meeting on

1-Methylcyclopropene (1-MCP) Exemption from Tolerance

Petition, and 1-MCP 0.14% and 3.3% Formulation EUP and Section 3

Food-Use Petitions

I would like to again thank you and your colleagues for meeting with us to discuss a number of items pertaining to our 1-MCP food-use registration petitions. My understanding of the major points we discussed and agreed-upon follow-up actions are indicated below:

### Participants:

EPA BPPD:

Driss Benmhend Sheryl Reilly Russell Jones Freshteh Toghrol Rohm and Haas Company: Stephen Longacre George Hazelton

## Clarification of EthylBloc Technology Ownership:

Rohm and Haas Company has changed the name of its subsidiary holding the registrations for EthylBloc Technology (EPA Reg. No. 71297-1 and 71297-EUP-1) to AgroFresh, Inc. (formerly BioTechnologies for Horticulture, Inc). Documentation for this name change, along with label amendments for our EthylBloc Section 3 food use petition (filed 06Apr00) and for our EthylBloc apple Experimental Use Permit (approved 12Oct00), were submitted to the Agency 20Nov00.

# 1-MCP Exemption from Tolerance Petition and EthylBloc Technology Section 3 Food-Use Registration:

Our 1-MCP exemption from tolerance petition (Rohm and Haas Report 00R-1012) and our Section 3 petition for the food-use registration of EthylBloc Technology (0.14% 1-MCP) were submitted to the Agency 06Apr00. You indicated that the reviews of the exemption from tolerance petition and food-use registration were scheduled for completion by end Feb '01. The drafting, review, and publication of the Final Rule for the exemption from tolerance in the Federal Register will take 1-2 months after the reviews are completed. The notification of the Section 3 registration would be mailed very soon after publication of the Final Rule. It is too early to tell if any additional data will be required prior to acceptance of these petitions, but there is nothing immediately pressing.

Valent BioSciences submitted comments to our notice of filing published 21Jun00. We submitted responses to Valent BioSciences' comments to the Agency 19Dec00. Please feel free to use our comments in your responses to Valent BioSciences' comments. Dietary and worker risk assessments for 1-MCP are included in our response.

<u>Action</u>: D. Benmhend to insure the reviewer, R. Jones, has a copy of our responses to Valent BioSciences' comments for his use.

Rohm and Haas has recently prepared a document on the air dispersion modeling of 1-MCP from a controlled atmosphere facility, that conservatively estimates very low (< 1 ppb) concentrations of 1-MCP in the atmosphere upon venting from the treatment room.

Action: S. Longacre will submit this air dispersion document (Rohm and Haas Report 00R-1066) to EPA (done).

## EthylBloc Technology EUP:

The EUP on our 0.14% formulation that was approved and initiated last October is in progress. The company where the trial is being conducted (Stemilt) wants the room emptied in April after only 6 months, rather than 9 months. This will be very close to the time the tolerance exemption is likely to be published. I will submit a petition to amend this EUP to a crop non-destruct EUP after the exemption from tolerance has been published as per your advice.

### AgroFresh™ Technology:

We have developed a process to manufacture a 3.3% 1-MCP in formulation. The brand name for this 3.3% product will be AgroFresh<sup>TM</sup>
Technology. This formulation will be much more convenient to use for food-use treatment compared to the 0.14% formulation. The maximum amount of ai released into a treatment room will remain at 1 ppm v/v regardless which formulation (3.3% or 0.14%) is used. The difference is that it will take only about 1/25th as much of the 3.3% product to accomplish this compared to the 0.14% product.

#### 3.3% Product EUP:

I showed several pictures to give the flavor of how big commercial apple storage facilities really are. A 2500 m³ storage room (about 30 feet wide, 70 feet long, 35 feet high) will contain about 2000 bins of apples (each bin = 900 lb apples); thus each room contains about 1,800,000 lb of apples. You indicated that an EUP for 180 room-treatments, which would utilize 3% of total US harvested apples, would not be approved. We probably would not get approval for an EUP much different from our current 6 trial EUP for the 0.14% formulation. We would need to clarify expected learnings from a new EUP. Your advice is to wait until the review of our exemption from tolerance petition is completed at the end of February to see if anything else would be required before submitting an EUP for the 3.3% product. The EUP for the 3.3% product would need to be crop destruct in the absence of the tolerance exemption approval. It might be best simply to submit the 3.3% Section 3 petition as soon as possible, but it is unlikely that this petition would be reviewed and approved by end of July/early Aug '01 in time for the apple post-harvest treatment season.

We briefly discussed a proprietary 1-MCP releasing system in which a sustomered designed generator already containing the powdered 1-MCP formulation was shipped to the customer. The customer would add water, turn on the CO<sub>2</sub> tank, push the plunger to mix the powder with the water, and the worker would immediately leave and seal the room. This will likely result in negligible worker exposure. Our response to Valent BioSciences' comments contains a worker risk assessment, and shows acceptable margins of safety even in worse-case situations.

#### Alternate 0.14% Formulations:

We are considering two alternate formulations. The first would be 0.14% 1-MCP,

This formulation would facilitate the release of 1-MCP out of the aqueous solution and into the atmosphere via effervescent action. You indicated that a Confidential Statement of Formula plus a description of how the formulation is prepared submitted as an alternate

formulation is probably all that is needed for approval of this formulation. The second formulation would be 0.14% 1-MCP plus indicated that a CSF submitted as an alternate formulation is likely all that would be needed, since this alternate formulation is simply a different ratio of the inert ingredients from an already approved formulation.

### Additional Toxicology and Residue Studies:

We discussed the ongoing studies we are conducting in support of our 3.3% formulation petition. These studies include the following:

- Product chemistry;
- 5 acute tox studies conducted with 3.3% formulation;
- rat 4 hr acute inhalation and mouse in vivo micronucleus assay conducted with 1000 ppm v/v 1-MCP gas; and
- 3 mutagenicity studies in which the agar plates or aqueous cell systems are exposed to an atmosphere of 1000 ppm v/v 1-MCP gas.

These studies will be submitted in Mar '01 as part of our Section 3 and EUP submissions for the 3.3% formulation.

We also discussed additional studies we are conducting or plan to conduct in support of our non-US 1-MCP registrations:

- Rat inhalation developmental toxicity (no developmental toxicity observed up to and including exposure to 1000 ppm v/v 1-MCP, report in preparation);
- Rat two-week range-finding inhalation study (minimal blood and spleen effects observed, report in preparation);
- Rat 90-day inhalation study (to initiate Feb '01, final report target 31Augu1);
- 14C-1-MCP small chamber apple residue study (methods development in progress);
- <sup>14</sup>C-1-MCP rat toxicokinetic study (to initiate Mar/Apr '01, final report target 31Aug01),

You indicated that it is not likely that the reviews of the exemption from tolerance petition or the 0.14% Sec 3 registration petition will be held up pending submission and review of any or all of the developmental tox, two-week- or 90-day, or residue studies, since final reports will not be available until later in the year. We will submit all 1-MCP tox and residue final reports to you upon completion.

#### Miscellaneous Items:

Action: D. Benmhend to insure MRID numbers are/were assigned for our 1-MCP exemption from tolerance petition (Rohm and Haas Report 00R-1012) and our study waiver document (Rohm and Haas Report AGREG-00-02) in support of the 0.14% EthylBloc food use petition;

Action: D. Benmhend to facilitate review of our 26Sep00 submitted alternate formulation (0.14% 1-MCP,

Action: D. Benmhend to review our 24Aug00 submitted placard for truck flower use instructions.

Please let me know if I have overlooked something or have not accurately captured any key points or action items. I can be reached by phone (215-592-3581), fax (215-592-3414), or Email (rstysl@rohmhaas.com) if you have any questions.

Sincerely,

Stephen L. Longacre, Ph.D.... Product Registration Martager

Agricultural Chemicals Registration

and Regulatory Affairs Department

CC:

Sheryl Reilly (EPA/BPPD)

Russell Jones (EPA/BPPD)

Freshteh Toghrol (EPA/BPPD)

George Hazelton (Rohm and Haas)

# BPPD PRAT ACTION CODING FORM

AGro Fresh In PM 90: Janet Anderser	.c.	REVIEWER: Driss  (ASSIGNED BY: LH
EPA REG./FILE SYMBO	DL 71297-1	- Alternate formulation
ACTION CODE 345		Amendment
(NEW a.i./EUPs/Tolera	aces: YesN	·
SUBMISSION BARCOL	E S 593311	
TE ON APPLICATION	ON 2/10/	
EPA RECEIVED DATE	2/2/01	
PM RECEIVED DATE		
ASSIGNED IN PRAT:		· 
COMPLETED BY:	h#	DATE: 3/1/01
<u> </u>	9 <del>000000000000000000000000000000000000</del>	<del>-</del> <u>000000000000000000000000000000000000</u>
PINAL ACTIO	N	
Response Code		
Response Date:		
MOS:(1	Cite-All	
(4	Not Applicable	
(8	) Selective	
CRP:	Yes No	_
Restricted Use:	YesNo	_
Manufacturing Use:	YesNo	
Exclusive Use:	Yes No	2/13

AMENDMENT

# APPLICATION FOR AMDENDMENT

WITH DATA		WITHOUT DATA		
INIT.	DATE	INIT.	DATA	
FEU		FEU Year	2-9-0	
SIG. (DATA)		PM 92		
PM				
	OPP# 2	75862		



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

02/07/2001

STEPHEN L. LONACRE TECHNOLOGY SCIENCES GROUP, INC. 100 INDEPENDENCE MALL WEST, PHILADELPHIA PA 19106

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PRODUCT NAME: ETHYLBLOC TECHNOLOGY COMPANY NAME: AGROFRESH, INC. OPP IDENTIFICATION NUMBER: 275862 EPA REGISTRATION NUMBER: 71297-1 EPA RECEIPT DATE: 02/02/2001

SUBJECT: RECEIPT OF AMENDMENT

#### DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Phil Hutton, Product Manager 92, at (703) 308-8260.

Sincerely,

- Jurice

Front End Processing Staff
Information Services Branch
Program Management and Support Division

**United States** X Amendment **Environmental Protection Agency** Washington, DC 20460 Other **Application for Pesticide - Section I** 2. EPA Product Manager 3. Proposed Classification 1. Company/Product Number **Driss Benmhend** 71297-1 4. Company/Product (Name) entitled to confidential treatment\* Restricted X None EthyiBloc® Technology 5. Name and Address of Applicant (Include Zip Code) 6. Expedited Review, in accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling AgroFresh, Inc. (formerly BioTechnologies for Horticulture, Inc.); a subsidiary of Rohm and Haas Company EPA Reg. No. \_ 100 Independence Mall West Philadelphia, PA 19106-2399 Product Name: ☐ Check if this is a new address Section - II Final printed labels in response to Amendment - Explain below. M Agency letter dated Resubmission in response to Agency letter dated \_\_\_ "Me Too" Application. Notification - Explain below. Other - Explain below. Explanation: Alternate formulation for EthylBloc (active ingredient = 1-methylcyclopropene) containing approximately with 0.14% 1-methylcyclopropene. Section - III 1. Material This Product Will Be Packaged In: þe Water Soluble Packaging 2. Type of Container Child-Resistant Packaging **Unit Packaging** Yes\* Yes Yes Metal \*Inert ingredient information may No **Plastic** No No No. per No. per Glass Unit Packaging wgt. container Package wgt container Paper \* Certification must Other (Specify) be submitted 3. Location of Net Contents Information 4. Size(s) Retail Container 5. Location of Label Directions Label Container On Label On Labeling accompanying product Other 6. Manner in Which Label is Affixed to Product Lithograph Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name Telephone No. (Include Area Code) 215 - 592-3581 Stephen L. Longacre, Ph.D. **Product Registration Manager** Certification 6. Date Application I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. Received ... I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. 3. Title 2. Signature **Product Registration Manager** 5. Date

February 01, 2001

White - EPA File Copy (original)

Please read instructions on reverse before completing form.

Stephen L. Longacre, Ph.D.

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

Yellow Applicant Copy

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

Registration

**OPP Identifier Number** 

Form Approved, DMB No. 2070-0080



# United States

**OPP Identifier Number** Registration

Washington	n, DC 20480	Amendment Other	275862
App	plication for Pesticide - Se	ection I	
1. Company/Product Number	2. EPA Product N	lenager 3. P	roposed Classification
4. Company/Product (Name)	PM#		None Restricted
5. Name and Address of Applicant (Include ZIP Code)  Check If this is a new address	(b)(i), my produ to: EPA Reg. No.		
Oten a and a stem and	Product Name	e	
	Section - II	7	
Amendment - Explain below.  Resubmission in response to Agency latter date  Notification - Explain below.	Agency "Me Too	nted labels in response to letter dated o" Application. Explain below.	
Explanation: Use additional page(s) if necessary. (			
	Section - III		
1. Material This Product Will Be Packaged In:			
	Ves No If "Yes" No. 11 Package wgt No. 12 Package wgt		r  Specify
3. Location of Nat Contents Information 4.	Size(s) Retail Conteiner	5 Location of Label Direct On Label On Labeling acco	ions
6. Manner in Which Lebel is Affixed to Wodust	Paper glued Stanciled	ther	20,11
	Section - IV	3 5 1	
1. Contact Point (Complete Nams directly below for it	dentification of individual to be contact	ed, if necessary, to process the	is application.)
Name	Title	Telepho	ne No. (Include Area Code)
I certify that the statements I have made on this I acknowledge that any knowingly falsa or misle both under applicable law.			6. Dete Application Received (Stamped)
2. Signature	3. Title		
4. Typed Name	5. Date	17-17-17	

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to everage 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send completing regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Brench, (2136), U.S. Environmental Protection Agancy, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1, Certification with Respect to Citation of Date (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formule (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling:
- 5. Three copies of any date submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of dreft labels with all applications for new registration. Such draft labels mey be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This eaction must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behelf of enother party, you must submit authorize to from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other posticide products that are ourrantly registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to emend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, past or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Peckaging Check the appropriate block if your product will be packaged in the indicated packaging types.

  Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

è Please read instructions on r	everse before completing form.	Form	Approved. OMB No. 2070-006	# # # # # # # # # # # # # # # # # # #
<b>≎EPA</b>	United States Environmental Protecti Washington, DC 20	ion Agency	Registration Amendment Other	OPP Identifier Number
	Applicati	on for Pesticide - S	Section I	
1. Company/Product Number		2. EPA Product	Manager 3.	Proposed Classification
4. Company/Product (Name)		PM#	L	None Restricted
5. Name and Address of Apple	is a new address	(b)(i), my prod to: EPA Reg. N	Review. In accordance with duct is similar or identical in co	
		Section - II		
Resubmission in resp  Notification - Explain	onse to Agency letter dated	Agence "Me T	orinted labels in response to by letter dated oo" Application Explain below.	
		Section - III		
1. Material This Product Will	Be Packaged in:			
Child-Resistant Packaging Yes* No Certification must be submitted	Unit Packaging Yes No No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packagis Yes No If "Yes" Package wgt No.	Metal Plasti Glass Paper	<b>c</b>
3. Location of Net Contents	Information 4. Size(s) R	etail Container	5. Location of Label Direct On Label	ctions
6. Manner in Which Label is	Affixed to Product Liths	ograph	Other	onpanying product
	Sten	Section - IV		
1. Contact Point   Complete	items directly below for identification	tion of individual to be conta	ected, if necessary, to process to	his application.)
Name		Title	Teleph	one No. (Include Area Code
	Certific ments I have made on this form an by knowingly false or misleading st law.	nd all attachments thereto e		6. Date Application Received (Stamped)
2. Signature		3. Titie		

5. Date

Yellow - Apilcant Copy

4. Typed Name

#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send completing the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Streat, SW, Washington, DC 20480.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, emendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process en application for a new registration submitted on this form, the following meterial must accompany the application:

- 1. Certification with Respect to Citation of Date (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling:
- 5. Three copies of any data submitted;
- 6. Authorization latter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mookup of the proposed label. If prepared for mookup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mookup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you ere submitting this form.

SECTION 1 - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrent, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be epecific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person end address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (o) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are ourrently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation end labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to en Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to e specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block end provide the Agency letter dete if appropriats. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Peckaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be peckaged in the indicated packaging types.

  Indicate the size of the individual packets and number per reteil container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is ettached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration ections, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.





February 1, 2001

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U. S. Environmental Protection Agency
Mr. Driss Benmhend
Biopesticides and Pollution Prevention Division
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

SLL-01-042

Dear Mr. Benmhend:

Subject:

EthylBloc® Technology (EPA Regis. No. 71297-1)

Active Ingredient = 1-Methylcyclopropene

**Alternate Formulation Amendment** 

AgroFresh, Inc. (formerly BioTechnologies for Horticulture, Inc.), a fully-owned subsidiary of Rohm and Haas Company, submits an alternate formulation for EthylBloc® Technology which contains 0.14% 1-methylcyclopropene (1-MCP) active ingredient. The proposed alternate formulation contains a maximum amount of

compared to currently approved formulations of EthylBloc\*. No other ingredients have been added to the formulation, and the concentration of 1-MCP active ingredient remains at 0.14%. A Confidential Statement of Formula (CSF) showing the composition of the proposed new alternate formulation of EthylBloc\* Technology is attached.

Please contact me by phone (215-592-3581), fax (215-592-3414), or email (rstysl@rohmhaas.com) if you have any questions about this submission.

Sincerely,

Stephen L. Longacre, Ph.D. Product Registration Manager

Agricultural Chemicals Registration and Regulatory Affairs Department

Mr. D. Bemnhend 01Feb01 Page 2

Administrative materials submitted with this letter:

- 1) EPA Form 8570-1 (OPP Identifier 267602);
- 2) Confidential Statement of Formula; EthylBloc; Alternate Formulation; 01Feb01.

453171-00



January 29, 2001

Document Processing Desk (7504C)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Mr. Driss Benmhend
Biopesticides & Pollution Prevention Division
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

SLL-01-037

Dear Mr. Benmhend:

Subject: EthylBloc® Technology (EPA Reg. No. 71297-1)

Active Ingredient = 1-Methylcyclopropene

Food-Use Section 3 Registration Petition (OF 6144)

Air Dispersion Modeling Study

Rohm and Haas Company, and its subsidiary AgroFresh, Inc. (formerly BioTechnologies for Horticulture, Inc.), submits the attached 1-methylcyclopropene (1-MCP) air dispersion modeling study in support of our EthylBloc Technology food-use Section 3 registration petition (OF 6144), originally submitted 06Apr00.

The report presents results of reasonable worst-case air dispersion modeling for 1-MCP after release from insulated concrete controlled atmosphere storage rooms used to treat fruit. The modeling exercise used a standard EPA air dispersion model (Industrial Source Complex ISCST3), and a reasonable worst-case exposure scenario to predict downwind airborne concentrations of 1-MCP at defined distances from the venting source. Results indicate that worst-case predicted airborne concentrations of 1-MCP quickly fall well below 1 ppb.

Please assign an MRID number to this study, and contact me by phone (215-592-3581), fax (215-592-3414), or email (rstysl@rohmhaas.com) if you have any questions about this report.

Sincerely,

Stephen L. Longacre, Ph.D.
Product Registration Manager
Agricultural Chemicals Registration

It Lorgane

and Regulatory Affairs Department

EPA/D. Benmhend 29Jan01 Page 2

## Attachments (report in triplicate):

Guideline Reference Number	Rohm and Haas Company Report Number	Report Title	MRID	
NA	00R-1066	W. D. Shade; 1-Methylcyclopropene (1-MCP): Industrial Source Complex (ISCST3) Dispersion Modeling of Air Emissions from Controlled Atmosphere Facilities; 17Jan01	4531710	

## Additional Attachment:

1) EPA Form 8570-1 (OPP Identifier Number 250075)

I, Sheryl K. Reilly, Chief, Biochemical Pesticides Branch, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the products may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product. Further, the recipient of this letter is on notice that the status of the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration and/or the product label for the product listed below. EPA has issued a registration number for the product listed below to:

Biotechnologies for Horticulture, Inc. 751 Thunderbolt Road Walterboro, SC 29488

## EPA REGISTRATION NUMBER

71297-1

## NAME OF PRODUCT

EthyBloc



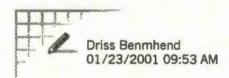
Sheryl K. Reilly, Chief

**Biochemical Pesticides Branch** 

JAN 19 2001

[Date]

	CONCURRENCES	
SYMBOL Reilly		
SURNAME 7516		
DATE 1-19-01		
EPA Form 1320-1A (1/90)		OFFICIAL PRECOPY



To:

Russell Jones/DC/USEPA/US@EPA

CC:

Subject: 1-MCP Toxicology Studies

----- Forwarded by Driss Benmhend/DC/USEPA/US on 01/23/2001 09:53 AM



Stephen\_L\_Longacre@RohmHaas.Com (Stephen L Longacre) on 01/18/2001 02:58:38 PM

To:

Driss Benmhend/DC/USEPA/US@EPA

CC:

Sheryl Reilly/DC/USEPA/US@EPA, George\_A\_Dr.\_Hazelton@RohmHaas.Com (George A Dr.

Hazelton)

Subject: 1-MCP Toxicology Studies

Driss,

As we discussed, we are developing 1-MCP for worldwide use, and, as you are well aware, some regulatory agencies outside of the US require more data than required by your Biopesticides Divison to register biochemical pesticide-like products such as 1-MCP. I indicated that we have initiated or plan to initiate several 1-MCP studies for both worldwide (non US) registrations and Product Stewardship reasons.

Attached is a summary of the ongoing and planned studies. The concentrations of 1-MCP administered in these studies were 100-1000 times greater than the 1 ppm proposed use concentration.

I mention these studies to you now, because the slight blood and spleen effects observed in the two-week rat range-finding inhalation study will likely require a FIFRA 6(a)2 submission within the next month (newly observed effects in a new tox study), and I wanted to let you know that you would be cc'd on this submission. It is possible that additional FIFRA 6(a)2 reports will be submitted during the year as we conduct these new toxicology studies. We can discuss further at Tuesday's meeting.

Regards,

Steve Longacre
Rohm and Haas Company
T: 215-592-3581
Email: rstysl@rohmhaas.com

tox2.doc

Meeting with R3H.

Description of leview Completed by end of fev.

And re everythe sk - 2 months to complete.

Publish final rule - 2 months to complete.

Ask of Steves Comments on the Comments received a

MRID # Check with there about MRID



December 12, 2000

Mr. Driss Benmhend
Biopesticides & Pollution Prevention Division
Office of Pesticide Programs (7511C)
U.S. Environmental Protection Agency
Room 902, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

SLL-00-292

Dear Mr. Benmhend:

Subject: EthylBloc® Technology (EPA Reg. No. 71297-1)

Active Ingredient = 1-Methylcyclopropene

**Request for Meeting** 

**Proposed Meeting Agenda** 

I request a meeting between EPA BPPD and Rohm and Haas in early to mid January, 2001 to discuss the following items:

- Status/timing of 1-methylcyclopropene (1-MCP) exemption from the requirement of tolerance petition;
- Status/timing of EthylBloc<sup>®</sup> technology (0.14% 1-MCP formulation) food-use registration;
- Timing of petition to amend current 0.14% EthylBloc apple EUP to crop non-destruct EUP;
- AgroFresh<sup>™</sup> technology (3.3% 1-MCP formulation) apple Experimental Use Permit filing and timing;
- 5) AgroFresh™ technology (3.3% 1-MCP formulation) Section 3 food-use registration filing and timing;
- 6) Data requirements for a 0.14% 1-MCP alternate formulation containing largely ; and
- 7) Data requirements for a 0.14% 1-MCP alternate formulation containing approximately

Items 1 and 2: AgroFresh, Inc. (formerly BioTechnologies for Horticulture, Inc.), a fully-owned subsidiary of Rohm and Haas Company, submitted a petition for an exemption from the requirement of tolerances for 1-MCP residues on food commodities, and a Section 3 registration petition for EthylBloc technology use on fruits and vegetables post harvest on 06Apr00. We would like to review the status and timing for review of these petitions to help us with our commercial planning.

D. Benmhend 12Dec00 Page 2

Item 3: We were granted approval in October, 2000 for a crop-destruct EUP for use of EthylBloc technology on apples. We would like to update the Agency on the status of this EUP, and discuss timing and the process for amending the EUP to a crop on non-destruct EUP. The treated apples will come out of storage in early April, 2001.

Items 4 and 5: We have developed a process for making a stable 3.3% 1-MCP formulation and are currently conducting acute toxicity, mutagenicity, and physical chemistry studies in support of an apple EUP and our Section 3 food-use registration petitions. We plan to file these petitions in mid to late. February, 2001, and request the Section 3 registration (or at least the crop non-destruct EUP) by July in time for the apple storage treatment season which runs from late August to early November.

Items 6 and 7: We are considering an 0.14% 1-MCP alternate formulation that ... contains mostly

. We are also considering a 0.14% 1-MCP alternate formulation

that contains

We would like to know what, if any, additional requirements the Agency might request for these alternate 0.14% formulations.

A two hour meeting is requested to discuss the above items, which are crucial for our commercial development plans. I request that Sheryl Reilly, the reviewer of the tolerance exemption and the 0.14% EthylBloc technology food-use petitions, and any other interested BPPD staff, in addition to yourself, attend. Rohm and Haas will be represented by Dr. George Hazelton (Toxicology Dept) and myself.

Please contact me by phone (215-592-3581), fax (215-592-3414), or email (rstysl@rohmhaas.com) with your availability.

Sincerely,

Stephen L. Longacre, Ph.D. Product Registration Manager

Agricultural Chemicals Registration and Regulatory Affairs Department

cc: Sheryl Reilly (EPA BPPD) George Hazelton (RH)



November 21, 2000

Mr. Driss Benmhend
Office of Pesticide Programs
Biopesticides & Pollution Prevention Division
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921Jefferson Davis Highway
Arlington, VA 22202-4501

SLL-00-275

Dear Mr. Benmhend:

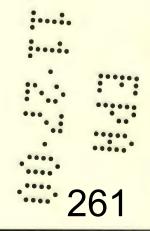
Subjects: EthylBloc® (EPA Reg. No. 71297-1-32258)

Active Ingredient = 1-Methylcyclopropene

**Clarification Sticker for Containers** 

Floralife, Inc. (Walterboro, SC) is our sub-registrant for EthylBloc use on flowers, potted plants, and ornamentals. Rohm and Haas Company's 1-methylcyclopropene (1-MCP) Section 3 food use and exemption from tolerance petitions will hopefully be reviewed and approved very soon. Because of the large amount of favorable interest and publicity generated so far regarding the future use of 1-MCP on food crops, we have requested Floralife, Inc. to add the following circular sticker to the containers of all of their EthylBloc flower-use products to clarify that EthylBloc may not yet be used on food or food crops.

NOT FOR USE ON FOOD OR FOOD CROPS



Mr. D. Benmhend 21Nov00 Page 2

We are asking Floralife, Inc. to do this to avoid any possible confusion in the marketplace before the 1-MCP food-use registrations are granted. We believe that the stickers are the fastest and most efficient manner to accomplish this clarification.

Please contact me by phone (215-592-3581), fax (215-592-3414), or email (rstysl@rohmhaas.com) if you have any questions about .

Sincerely,

Stephen L. Longacre, Ph.D. Product Registration Manager Agricultural Chemicals Registration

and Regulatory Affairs Department

cc: Sheryl Reilly / EPA BPPD

262



November 20, 2000

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
Mr. Driss Benmhend
Biopesticides & Pollution Prevention Division
U.S. Environmental Protection Agency
Room266A, Crystal Mall #2
1921Jefferson Davis Highway
Arlington, VA 22202-4501

SLL-00-273

Dear Mr. Benmhend:

Subjects: EthylBloc® Technology (EPA Reg. No. 71297-1; 71297-EUP-1)

Active Ingredient = 1-Methylcyclopropene

Change of Subsidiary Name Holding Registrations to

AgroFresh, Inc. (formerly BioTechnologies for Horticulture, Inc.)

Draft Label Amendments Indicating AgroFresh, Inc. Name

Rohm and Haas Company has changed the name of its subsidiary holding the registrations for EthylBloc® Technology (EPA Reg. No. 71297-1 and 71297-EUP-1) to AgroFresh, Inc. (formerly BioTechnologies for Horticulture, Inc.). I have attached documentation for this name change, and submit revised draft labels for our EthylBloc Section 3 food use petition (filed 06Apr00) and for our EthylBloc apple Experimental Use Permit (approved 12Oct00) indicating the name change to AgroFresh, Inc.

Please contact me by phone (215-592-3581), fax (215-592-3414), or email (rstysl@rohmhaas.com) if you have any questions about this name change or the amended draft labels.

Sincerely,

Stephen L. Longacre, Ph.D. Product Registration Manager

Agricultural Chemicals Registration and Regulatory Affairs Department

cc: Sheryl Reilly / EPA BPPD



751 Thunderbolt Rd Waterboro SC 29488 Phone: 843-538-3839

### Floralife Inc.



To:	Diar	a Hudson - US EPA	F	rom:	James Daly		
Fax:	703-	308-7026	D	ate:	November 29, 200	00	
Phone			P	ages:			
Re;	Reg	# 71297-1EthylBloc	С	C:			
Urgeni Recyc		x For Review	Please Commen	t	Please Reply	Please	
•Coma	nents						

Dear Ms Hudson

As per our phone conversation please release the requested gold seals to the Rohm and Haas Company. Also please note that Biotechnologies for Horticulture has been sold to Rohm and Haas. Please call me with any questions.

Jim Daly

Chief Operating Officer

Set 9: Tionalife, Inc.;

Biotechnologies For Harticulture, Inc. 751 Thunderbott Rd Walterboro, SC 29488

label date: 3/00



November 15, 2000

Diana Hudson
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

SLL-00-269

Dear Ms. Hudson:

Subject: Request for Gold Seal Letter for EthylBloc (EPA Reg No. 71297-1)

I request that EPA send me 10 copies of a gold seal letter for EthylBloc (EPA Registration No. 71297-1). EthylBloc is registered to BioTechnologies for Horticulture, Inc., which is a fully owned subsidiary of Rohm and Haas Company. Please send the letters to:

Stephen L. Longacre Rohm and Haas Company 100 Independence Mall West Philadelphia, PA 19106-2399

Please contact me by telephone at 215-592-3581 or email at rstysl@rohmhaas.com if you have any questions about this request.

Sincerely,

Stephen L. Longacre, Ph.D.
Product Registration Manager
Agricultural Chemicals Registration
and Regulatory Affairs Department

Rec'd. NOV 20 2000 BPPD

266

# BPPD PRAT ACTION CODING FORM

PM 90: Janet Ander	rsen		REVIEWER:	5k/2)
EPA REG./FILE SYN	IBOL 7/2	97-EU	P-R(01-13)	
ACTION CODE	744		Damend.	ful
(NEW a.i./EUPs/Tol	erances: Yes	/No_	_ Ulmi	
SUBMISSION BARC	ODE 558	1257	-167-2	
PATE ON APPLICA				
EPA RECEIVED DA			NOTE TO SECOND	
PM RECEIVED DAT	TE 10/13	00		
ASSIGNED IN PRA	r: YES X	NO	- / / -	
COMPLETED BY:_	T. Bell	ead	TE: 10/26/08	
000000000000000000000000000000000000000	000000000000000000000000000000000000000	9000000	00000000000000000000000000000000000000	
TINAL ACT	ION			
Response Code				0
Response Date:			Aviso	1/2 cm
MOS:	(1) Cite-All		P	J 4 316
article and the	(4) Not Appli	cable	de	po 30 7
3	_ (8) Selective		CAF.	of the SIG
CRP:	Yes	No	(1000)	Por
Restricted Use:	Yes	No	Sheet of the	
Manufacturing Use:	Yes	No	THE RESERVE OF THE PARTY OF THE	
Exclusive Use:	Yes	No	15 M. 119"	267



October 3, 2000

Mr. Driss Benmhend
Biopesticides & Pollution Prevention Division
Office of Pesticide Programs (7511C)
U.S. Environmental Protection Agency
Room 902, Crystal Mall #2
1921Jefferson Davis Highway
Arlington, VA 22202

SLL-00-233

Dear Mr. Benmhend:

Subject:

EthylBloc® Technology (EPA Reg. No. 71297-EUP- 1)

Active Ingredient = 1-Methylcyclopropene

Final Label for an Experimental Use Permit on Apples

Attached is a final label for an Experimental Use Permit for EthylBloc on apples. Again, we wish to register this product for experimental use to conduct large scale commercial indoor post-harvest trials of EthylBloc on apples later in mid October.

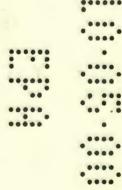
Please contact me by phone (215-592-3581), fax (215-592-3414), or email (rstysl@rohmhaas.com) if you have any questions about this final label.

Sincerely.

Stephen L. Longacre, Ph.D.
Product Registration Manager
Agricultural Chemicals Registration
and Regulatory Affairs Department

Administrative materials submitted with this letter:

- 1) EPA Form 8570-1 (OPP Identifier 264748);
- 2) EUP Label (EUP-1, 10/3/00) (5 copies)



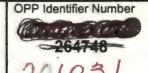
Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

**EPA** 

### United States Environmental Protection Agency

Amendment

Registration



Washington, DC 20460

Applicati	on for Pesticide - Section I	
Company/Product Number	2. EPA Product Manager	3. Proposed Classification
71297-EUP- R	Driss Benmhend	
4. Company/Product (Name)	PM#	
EthylBloc®		None Restricted
	10.5 - dh 15 day barren	SISDA O-E 2/-)/2)
5. Name and Address of Applicant (Include Zip Code)  BioTechnologies for Horticulture, Inc.; a subsidiary of Rohm and Haas Company 100 Independence Mall West Philadelphia, PA 19106-2399  Check if this is a new address	6. Expedited Review. In accord (b)(I), my product is similar or ide to:  EPA Reg. No.  Product Name:	ntical in composition and labeling
Check it this is a new address	Section - II	
Amandment Evalain below	Final printed labels in respor	area to
Amendment - Explain below.  Resubmission in response to Agency letter dated  Notification - Explain below.	Agency letter dated	ise to
Explanation: Revised draft label for EUP for EthylBloc u	se on apples removing all other crops excep	ot apples from EUP label.
	Section - III	
Material This Product Will Be Packaged In:	Section - III	
Child-Resistant Packaging Yes* No If "Yes" No. p  * Certification must be submitted  Unit Packaging Yes No. p  Unit Packaging wgt. contains	Yes No	e of Container  Metal  Plastic  Glass  Paper  Other (Specify)
Location of Net Contents Information	Size(s) Retail Container 5. Location	n of Label Directions
Label Container		n Label n Labeling accompanying product
6. Manner in Which Label is Affixed to Product	Lithograph Other Paper glued Stenciled	
	Section - IV	
1. Contact Point (Complete items directly below for identification)		
Name Stephen L. Longacre, Ph.D. Title		ephone No. (Include Area Code) - 592-3581
Certification I certify that the statements I have made on this form and all att I acknowledge that any knowingly false or misleading statement both under applicable law.	n tachments thereto are true, accurate and complet	6. Date Application
1 + 1 7 7	Title oduct Registration Manager	
4. Typed Name 5.	Date	••••
Stephen L. Longacre, Ph.D.	October 3, 2000	••••

**OPP Identifier Number** 



### United States ENVIRONMENTAL PROTECTION AGENCY

Washington, DC 20460

201031

Use a Pesticide for Exper	rimentai	Purposes Uniy		
1.Type of Application	2. Briefly	explain (attach a separate sheet	if necessary)	
New Amendment (See No. 2)				
Extension (Give Permit Rumber below)				
Permit Number				
Name and Address of Firm/Person to Whom the Experime Permit is to be Issued (include Zip Code) (Type or Print)	ental Use	4. Name and Address of Shippedifferent from applicant's na ( <i>Type or Print</i> )		
EPA Company Number		6. Is Product Registered with E	PA?	
5. Name of Product		No Yes (Give Registr Registration Number		r or File Symbol below)
7. Total Quantity of Product Proposed for Shipment/Use  Pounds of formulated product  Pounds of active ingredient	8. Acreage	or Area to be Treated 9. P	roposed Peri	od of Shipment/Use
10. Places from which Shipped	1	11. Crop/Site to be Treated		
12. Specify the name and number of the contact person mos with this application.	et femiliar	13. Signature of Applicant or A	uthorized Fir	m Representative
				77V 19 19 1
		14. Title		15. Date Signed
	Certific	cation		
This is to certify that food or leed derived from the experime except by laboratory or experimental animals, if illegal residult osrtify that the statements I have made on this form and all knowingly false or misleading statement may be punishable in	ental program ues are prese Il attachment	n will not be used or offered for int in or on such food or feed. Is thereto are true, accurate, and	l complete. I	
/	Balow for EP	A Line Only	24.	
In any correspondence on this application, refer to this numb	ber:		# <b>0##</b> 96 <b>199</b> 0006000808000000	by: Registration Division, on, DC 20460
Normal review time indicates that processing of this applicat	tion should b	e completed by (date)		
Name of EPA Contact Person	Telepho	nie Rümber		

**\$EPA** 

### United States

### **ENVIRONMENTAL PROTECTION AGENCY**

Washington, DC 20460

201031/

**OPP Identifier Number** 

Office of Pesticides Programs (7505C)

Application for Experimental Use Permit to Ship and

Use a Pesticide for Experi	mental Purposes Only
1.Type of Application	2. Briefly explain (attach a separate sheet if necessary)
New Amendment (See No. 2)	
Extension (Give Permit Number below)	
Permit Number	
3. Name and Address of Firm/Person to Whom the Experimen Permit is to be lesued (Include Zip Code) (Type or Print)	4. Name and Address of Shipper only if shipment is intended or if different from applicant's name and address (include Zip Code) (Type or Print)
EPA Company Number	6. Is Product Registered with EPA?
5. Name of Product	□ No
	Yes (Give Registration Number or File Symbol below)
	Registration Number
	File Symbol
7. Total Quantity of Product Proposed for Shipment/Use	B. Acteage or Area to be Treated 9. Proposed Period of Shipment/Use
Pounds of formulated product	X I I I I I I I I I I I I I I I I I I I
Pounds of active ingredient	
10. Places from which Shipped	11 to Crop/Site to be Treated
12. Specify the name and number of the contact person most with this application.	familiar 13. Signature of Applicant or Authorized Firm Representative
	14. Title 15. Date Signed
	Certification
except by laboratory or expérimental animels, if illegal residue	
knowingly false or misleading statement may be punishable by	ettachments thereto are true, accurate, and complete. I acknowledge that any fine or imprisonment, or both, under applicable law.
	plaw for EPA Use Only
In any correspondence on this application, refer to this number	Received by: EPA-OPP Registration Division,
	Washington, DC 20460
Normal review time indicates that processing of this application	on should be completed by (date)
<b>3.0</b>	
Name of EPA Contact Person	Telephone Humber
Name of EPA Contact Person	Telephone Number

**OPP Identifier Number** 



### United States ENVIRONMENTAL PROTECTION AGENCY

Washington, DC 20460

201031

COO'L COMOIGO TO EXPON	interitar i arpoeco omy	
1.Type of Application	2. Briefly explain (attach a separate sheet if necessar	y)
New Amendment (See No. 2)		
Extension (Give Permit Number below)		
Permit Number		
3. Name and Address of Firm/Person to Whom the Experime Permit is to be Issued (Include Zip Code) (Type or Print)	4. Name and Address of Shipper only if a different from applicant's name and ad (Type or Print)	
EPA Company Number	6. Is Product Registered with EPA?	
5. Name of Product	No Yee (Give Registration Number File Symbol	
7. Total Quantity of Product Proposed for Shipment/Use  Pounds of formulated product  Pounds of active ingredient		riod of Shipment/Use
10. Places from which Shipped	11. Crop/Site to be Treated	
12. Specify the name and number of the contact person mos with this application.	et familiar 13. Signature of Applicant or Authorized	Firm Representative
	14. Title	15. Date Signed
	Certification	
This is to certify that food or feed derived from the experime except by laboratory or experimental animals, if illegal residual certify that the statements I have made on this form and all knowingly false or misleading statement may be punishable to	es are present in or on such food or feed. I attachments thereto are true, accurate, and complete.	
	Selow for EPA Use Only	
In any correspondence on this application, refer to this numb	EPA-OF	d by: P Registration Division, gton, DC 20460
Normal review time indicates that processing of this applicati	ion should be completed by (date)	
Name of EPA Contact Person	Telephone Number	

**SEPA** 

### United States ENVIRONMENTAL PROTECTION AGENCY

Washington, DC 20460

201031/

**OPP Identifier Number** 

Use a Pesticide for Experi	imenta	I Purposes Only		
1.Type of Application  New Amendment (See No. 2)  Extension (Give Permit Number below)  Permit Number	2. Briefly	explain (attach a eeparate shee	t if necessery)	
3. Name and Address of Firm/Person to Whom the Experiment Permit is to be Issued (include Zip Code) (Type or Print)	ntal Use	4. Name and Address of Ship different from applicant's r ( <i>Type or Print</i> )		
EPA Company Number		6. Is Product Registered with	EPA?	
5. Name of Product		Registration Number		r or File Symbol below)
7. Total Quantity of Product Proposed for Shipment/Uee  Pounds of formulated product  Pounds of active ingredient  10. Places from which Shipped	8. Acreage	or Area to be Treated 9.	Proposed Perio	od of Shipment/Use
12. Specify the name and number of the contact person mos with this application.	et familiar	13. Signature of Applicant or	Authorized Fire	m Representative
		14. Title		15. Date Signed
	Certifi	cation		
This is to certify that food or feed derived from the experimental animals, if illegal residues I certify that the statements I have made on this form and all knowingly false or misleading statement may be punishable by	attachmen	ent in or on such food or feed. ts thereto are true, accurate, ar	nd complete. I	
	Jolow for E	PA Une Only		34277
In any correspondence on this application, refer to this numb	or			by: Registration Division, on, DC 20460
Normal raview time indicates that processing of this applicati	on should !	oe completed by (date)		
Name of EPA Contact Person	Teleph	one Number		Land Contraction

**SEPA** 

### United States

### **ENVIRONMENTAL PROTECTION AGENCY**

Washington, DC 20460

OPP Identifier Number

201031

1.Type of Application	2. Briefly	explein (ettach a seperate sheet if nece	essary)
New Amendment (See No. 2)			
Extension (Give Permit Number below)			
Permit Number			
3. Name and Address of Firm/Person to Whom the Experiment Permit is to be issued (include Zip Code) (Type or Print)	ntal Use	4. Name and Address of Shipper only different from applicant's name an (Type or Print)	
EPA Company Number		6. Is Product Registered with EPA?	
5. Name of Product		□ No	
		Yes (Give Registration !	Number or File Symbol below)
		Registration Number	
		File Symbol	
7. Total Quantity of Product Proposed for Shipment/Use	8. Acreage		ed Period of Shipment/Use
Pounds of formulated product			
Pounds of active ingredient		11. Crop/Site to be Treated	
12. Specify the name and number of the contact person mos with this application.	t familiar	13. Signature of Applicant or Authori	ized Firm Representative
		14. Title	15. Date Signed
	Certifi	cation	
This is to certify that food or feed derived from the experiment except by laboratory or experimental animals, if illegal residuents or certify that the statements I have made on this form and all knowingly false or misleading statement may be punishable by	attachmen	ent in or on such food or feed. ts thereto are true, accurate, and comp	plete. I acknowledge that any
	ielow for E	PA Lies Only	6-27
In any correspondence on this application, refer to this number	er e		celved by:
			A-DPF Registration Division. schington, DC 20460
Normal raview time indicates that processing of this applicati	on alsould l	se completed by (date)	
Name of EPA Contact Person	Teleph	one flumber	

### INSTRUCTIONS

Refer to 40 CFR 172 for regulations regarding experimental use permits. These regulations were published in the FEDERAL REGISTER on April 30, 1975 (40 FR 18780). Complete all (and only) numbered items on the application form. If an EPA Company Number (Item 2) has not previously been assigned, indicate "None," and a number will be assigned on your acknowledgment copy of the form. Third party applicants (those who will be testing another firm's registered product) need not complete Item 13. On the acknowledgment copy of this form, you will be assigned a File Number or Symbol for identification of this application. An expected completion date and the name of your EPA Contact will be entered. You may call your EPA Contact if you have not received your permit or a letter of explanation by the date indicated.

### Experimental Use Permit Data Submission

The following information must be submitted in triplicate and in detail (bound in removable sections A through G with margin tabs) for all new chemicals and many new products. For some new formulations, the information requested in Items C, D, E, and F may be included by reference to other formulations if adequate extrapolation may be made. Where the applicant requests permission to test a registered product, the information requested in Items B, E, F, and G below, along with the EPA Registration Number of the product, will usually suffice. Refer to 40 CFR 158.640 [53 FR 15993, May 4, 1988] for further information.

- A. A data sheet giving the chemical and physical properties of the chemical. A complete statement of the names and pepercentages by weight of each Active and Inert ingredient in the formulation to be shipped. This information will be handled as condential material.
- B. One copy of the proposed label including directions for use necessary for evaluation of the product. Refer to 40 CFR 172.6 for minimum labeling requirements. In certain circumstances the experimental program or other supplemental labeling may be permissible in lieu of full labeling. In such cases, submit a full explanation as to how the labeling will be affixed to or accompany the container.
- C. Toxicity data or reference to available data on the toxicity of the pesticide including, where pertinent, data on the toxicity to fish and wildlife. Include a summary of this information. LD<sub>so</sub> values and results of eye irritation studies on the formulated product must be included.
- D. Residue data, where pertinent, on (a) food or feed commodities; (b) nonfood crops such as tobacco; and (c) foliage or other sites which may relate to worker hazard or adverse effects on the environment. Include a description of the analytical method(s) used and a summary of the data.
- E. Effectiveness data [required only if specified in Regulations 40 CFR 158.640, 53 FR 15993, May 4, 1988 and Registration Guidelines 40 CFR 158.202(i), 53 FR 15993, May 4, 1988].
- F. If the pesticide is to be tested in a manner involving food or feed, and an adequate tolerance is not established to cover the use, file a petition for a temporary tolerance with this Agency and forward three copies with this application. If appropriate tolerances are established already, cite applicable Regulation in Title 40 of the Code of Federal Regulations.
- G. Proposed Experimental Program: (1) Give the qualifications and the names, addresses, and telephone numbers of the individuals (participants) who will supervise the experimental work.
  - (2) Name the States in which the pesticide will be used and the acreage to be treated in each State. Where MacreageM does not apply, give extent of testing per State in more appropriate terminology. Indicate separately any other State(s) to which the pesticide may be shipped for further distribution.
  - (3) Give the details of the proposed program including the types of target pests or organisms, the crops, animals, surfaces, materials, buildings, or sites of application to be treated and the major geographical areas where the material is to be used. For seasonal pests or crops, indicate the desired month for pesticide application to begin. Specify the use pattern, intended plot sizes, number of plots, number of replicates, dosage rates, methods of application, season of use (spring, summer, fall) and timing of application (preplant, postemergence, multiple (indicate pattern and number), etc.).
  - (4) List the objectives of the proposed program including, e.g., what type(s) of data will be collected during the testing period (performance, yield, phytotoxicity, environmental residue, etc.). Indicate your long-range testing plans, including how many years you expect to conduct experimental testing in support of registration of this use. This information will be helpful in evaluating the currently proposed program.
  - (5) Submit an explanation to Justify the quantity of the material requested, including various parameters used to determine the quantity. Quantities authorized will be based on the program submitted and consideration of the types and amount of data required to support registration.
  - (6) Propose a suitable duration for the permit commensurate with the program. Any request for a period greater than 1 year must be adequately justified.
  - (7) State the method of disposition of any unused material left at the conclusion of the testing program.

### Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average three quarters of an hour including time for reviewing instructions, gathering existing product sources and addresses, shippers to be used and addresses, and completing this instrument. Send comments regarding this estimate or any other aspect of this process, including suggestions for reducing the burden to: Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460; Office of Management and Budget, Paperwork Reduction Project (2070-0040), Washington, DC 20503.

NOTE: Applicant may retain last copy (04-14-93)

### EthylBloc® Technology Application for Experimental Use Permit on Post-Harvest Apples

### Section B

### **Proposed Labeling**

EthylBloc® Technology (EPA Reg. No. 71297-EUP-\_\_\_)

Active Ingredient: 1-Methylcyclopropene (1-MCP); CAS No. 3100-04-7

This section contains the proposed label for EthylBloc for indoor post-harvest use on apples. During the Experimental Use Permit program, use of the product will be restricted to application to apples. Directions for how much EthylBloc end-product formulation to use to release an effective concentration of 1-MCP active ingredient into a defined treatment chamber volume is indicated on the label.

The labeling included in this section is sufficient to support an application under FIFRA Section 5 for an Experimental Use Permit for the use of EthylBloc on a Raw Agricultural Commodity (RAC) crop, Apples.



### FOR EXPERIMENTAL USE ONLY

Not for sale to any person other than a Participant or Cooperator of the EPA approved Experimental Use Program. For use only at an application site of a cooperator in accordance with the terms and conditions of the Experimental Use Permit. This labeling must be in the possession of the user at the time of the pesticide application.

BioTechnologies for Horticulture, Inc. A subsidiary of Rohm and Hasa Company Philadelphia, PA. 19106 Tel: (215) 592-3000

# EthylBloc<sup>o</sup> Technology

Active Ingredient: 1-Methylcyclopropene	0.14%
Other Ingredients:	. 99.86%
Total:	100.00%

**EPA REG. NO. 71297-EUP-**

NOTICE: Before using this product, read the entire Precautionary Statements, Conditions of Sale and Warranty, Directions for Use, Use Restrictions and Storage and Disposal Instructions. If the Conditions of Sale and Warranty are not acceptable, return the product unopened within thirty days of purchase to the place of purchase.

## KEEP OUT OF REACH OF CHILDREN CAUTION

#### FIRST AID

IF IN EYES: Flush with plenty of water for at least 15 minutes. Call a physician if irritation persists. IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF SWALLOWED: Dilute by drinking 1 or 2 glasses of water and call a physician.

#### **Net Contents:**

1.34 oz. [38 grams (water soluble packet)],
2.6 oz. [75 grams (water soluble packet)] and 3.5 oz. [100 gram botte]

#### PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and mixers of this product must wear:

- Long-sleeved shirt and long pants.
- Shoes plus socks.
- Protective eyewear (goggles or face shield).
- Rubber gloves.
- As a general precaution when exposed to a volatile material, for activities in enclosed areas, wear a
  respirator with either an organic vapor-removing cartridge with a prefilter approved for pesticides
  (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides
  (MSHA/NIOSH approval number prefix TC-14G).
- Applicators and handlers must follow manufacturer's instructions for cleaning / maintaining PPE. If
  no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately
  from other laundry.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling and the terms of the Experimental Use Permit.

### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Workers Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours from the initial release of the volatile active ingredient.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, is:

- Long-sleeved shirt and long pants
- Rubber gloves
- Shoes plus socks
- Protective eyewear
- Respirator

#### CONDITIONS OF SALE AND WARRANTY

This product is for EXPERIMENTAL USE ONLY. BioTechnologies for Horticulture, Inc./Rohm and Haas Company makes no warranties or merchantability or fitness for a particular purpose nor any other express or implied warranty except as stated herein.

#### GENERAL INFORMATION

EthylBloc® technology (ripening control agent) is a powder that, when mixed with water, releases the volatile active ingredient 1-methylcyclopropene (1-MCP) which counteracts many of the undesirable effects of ethylene in harvested apples.

EthylBloc works by blocking the effects from both internal and external sources of ethylene.

EthylBloc is very effective at counteracting many of the undesirable effects of ethylene on harvested apples, like accelerating ripening and softening, and physiological disorders.

EthylBloc can be used immediately after harvest, prior to short-term or long-term storage or just prior to shipment and upon arrival from the supplier. EthylBloc is more effective under warm temperature conditions, 55° to 75°F, (13° to 24° C). Longer treatment times are required for apples held under temperatures below 55°F, (13° C).

### POST-HARVESTED APPLES

Harvested apples must be exposed to the volatile active ingredient of EthylBloc in enclosed areas such as storage rooms, greenhouses, coolers, shipping containers, enclosed truck trailers, plastic bags of at least 3 mil (63µm in thickness), or large controlled atmosphere food storage facilities. These enclosed areas should be fairly gas tight as excessive leakage will reduce EthylBloc effectiveness. This product is not intended for use outdoors or in other non-enclosed areas.

EthylBloc can be applied immediately after harvest, upon entering storage, in transit or at the distribution center. TABLE 1 gives the quantity of EthylBloc needed for treatment per room size. TABLE 2 indicates the dosage of EthylBloc recommended for apples.

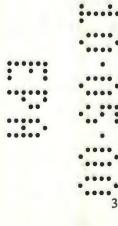


TABLE 1

Application rates of EthylBloc technology for 1, 300 and 1000 m<sup>3</sup> chambers, and volume of water needed to release 1-MCP into the air.

1 m <sup>3</sup> Chamber		300 m <sup>3</sup>	Chamber	1000 m <sup>3</sup> Chamber		
grams EthylBloc	water (ml)	grams EthylBloc	water (liters)	grams EthylBloc	water (liters)	
0.05	0.8	15	0.24	50	0.8	
0.16	2.5	48	0.75	160	2.5	
0.32	5	96	1.5	320	5	
0.48	7.5	144	2.25	480	7.5	
0.64	10	192	3.0	640	10	
0.80	13	240	3.9	800	13	
0.96	15	288	4.6	960	15	
1.12	18	336	5.4	1120	18	
1.28	20	384	6.0	1280	20	
1.44	23	432	6.9	1440	23	
1.60*	25	480*	7.5	1600*	25	

Note:  $1 \text{ m}^3 = 35.3 \text{ ft}^3$ 

TABLE 2
Application rates of EthylBloc technology for post-harvest apples:

Crop	Response Affected	grams EthylBloc/m <sup>3</sup>	Volume of release water (ml/m <sup>3</sup> )
Apples	Firmness and scald	0.8 - 1.6	12.5 - 25

EthylBloc is more effective when apples are exposed to the volatile active ingredient for at least 6 to 12 hours under warm temperature conditions (55°F to 75°F, 13°C to 24°C). Higher use rates and longer treatment periods of at least 12 to 24 hours are required for applications at lower temperatures (below 55°F, 13°C).

#### To treat with EthylBloc in large volume chamber:

- 1. Measure the volume of the chamber/room/trailer in cubic meters or cubic feet.
- Determine the number of grams of EthylBloc product and volume of water needed based on chamber volume and desired dosage of EthylBloc.
- 3. To mix:
  - a. Wear all Personal Protective Equipment (PPE) required under the Precautionary Statements.
  - b. First add warm water to mixing container (40° C ideal).
  - C. Then add the calculated amount of EthylBloc powder to the mixing container in the treatment chamber.
  - d. Briefly stir the mixture for 4-5 seconds and immediately leave the treatment chamber making sure the chamber is properly sealed.

<sup>\*</sup>Amount EthylBloc needed to release approximately 1000 ppb (v/v) 1-MCP into the air in the respective chamber volume.

- e. Alternatively, a remote location mixing device may be used.
- f. POSTING: Signs should be posted on all potential entry points during EthylBloc treatment Signs should state "CAUTION. Do not enter area. EthylBloc technology treatment progress." Posting is recommended as a means of ensuring optimal effectiveness of Ethylbloc.

**Example:** Treat apples with 0.8 g EthylBloc product per m<sup>3</sup> in a sealed 5°C cold room measuring 3 m wide x 10 m long x 4 m high.

- 1.  $3 \text{ m} \times 10 \text{ m} \times 4 \text{ m} = 120 \text{ m}^3$ .
- 2.  $0.8 \text{ g} \times 120 \text{ m}^3 = 96 \text{ g of EthylBloc}$ .
- 3. In mixing container, add 1.5 liters of water that is heated to 40°C.
- 4. Stir in EthylBloc (96 g) and seal room.
- 5. Maintain seal for desired treatment period.
- 6. After treatment period is complete, vent the active ingredient vapors from the room.
- 7. The room can now be opened and crops stored, processed or shipped.
- 8. Remaining treatment solution can be disposed of on site or at an approved waste disposal facility.

### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original packaging in a cool, dry place.

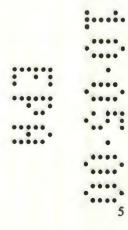
Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

EthylBloc is a registered trademark of BioTechnologies for Horticulture, Inc./Rohm and Haas Company

BioTechnologies for Horticulture, Inc. A Fully-Owned Subsidiary of Rohm and Haas Company 100 Independence Mall West Philadelphia, PA. 19106 (215) 592-3000

EUP-1 SL/rdm 10/3/00



ROHM HAAS COMPANY

September 26, 2000

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U. S. Environmental Protection Agency
Mr. Driss Benmhend
Biochemical Pesticides Branch
US EPA Biopesticides and
Pollution Prevention Division
Office of Pesticide Programs
1921 Jefferson Davis Highway, CM2
Arlington, VA 22202

SLL-00-227

Dear Mr. Benmhend:

Subject:

EthylBloc® (EPA Regis. No. 71297-1)

Active Ingredient = 1-Methylcyclopropene

**Alternate Formulation Amendment** 

BioTechnologies for Horticulture, Inc. (BTH)/Rohm and Haas Company submits an alternate formulation for EthylBloc®, which contains 0.14% 1-methylcyclopropene (1-MCP) active ingredient. The proposed alternate formulation contains

compared to currently approved formulations of EthylBloc®.

No other ingredients have been added to the formulation, and the concentration of 1-MCP active ingredient remains at 0.14%. A Confidential Statement of Formula (CSF) showing the composition of the proposed new alternate formulation of EthylBloc® is attached.

Please indicate the Agency's approval of this alternate formulation to me at your earliest convenience; this alternate formulation will not be produced until I receive the Agency's approval. Please contact me by phone (215-592-3581) or email (rstysl@rohmhaas.com) if you have any questions about this submission.

Sincerely,

Stephen L. Longacre, Ph.D. Product Registration Manager

Agricultural Chemicals Registration

Mr. D. Bemnhend 26Sep00 Page 2

Administrative materials submitted with this letter:

- 1) EPA Form 8570-1 (OPP Identifier 264747);
- 2) Confidential Statement of Formula; EthylBloc; Alternate Formulation; 26Sep00.

REGYCLING

Stephen L. Longacre, Ph.D.

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

Please read instructions on reve	erse before completing form	1.		Form Appro	oved. OMB No. 2		oval expires 05-31-9
<b>⊕EPA</b>	United S E <b>nvironmental Pr</b> Washington,	otection	Agency	X	Amendme Other	21	entifier Number 1897 267607
	Appli	cation for	Pesticide	- Section	n I		
1. Company/Product Numbe				oduct Manag		3. Proposed	Classification
71297-1			Driss B	enmhend			
. Company/Product (Name	)		PM#			1	
EthylBloc®				9 2	)	X None	Restricted
Name and Address of Ap	plicant (Include 7in Cod	(a)	6 Evnedi	ad Paviow	In accordance	with FIFRA Se	ection 3/c)/3)
BioTechnologies for Horti 100 Independence Mall V Philadelphia, PA 19106-	iculture / Rohm and Haa Vest	•	(b)(l), my p to: EPA Reg	roduct is sim	nilar or identical	l in composition	and labeling
☐ Check	t if this is a new address		Product	lame			
		Sec	ction - II				
Amendment - Explain t	pelow.			al printed labe	ls in response to		
Resubmission in respo	nse to Agency letter dated			Too" Applica			
Notification - Explain be	elow.		Oth	er - Explain b	elow.		
kplanation: Use additional Iternate formulation for Ethy with 0.14% 1-me		= 1-methylcy		containing a	pproximately		
. Material This Product W	/ill Be Packaged In:	060	, tion - in	-			
hild-Resistant Packaging Yes* No	Unit Packaging Yes No If "Yes"		Vater Soluble Yes No "Yes"	Packaging  No. per		Container Metal Plastic Glass	
Certification must	Unit Packaging wgt.	container P	ackage wgt	container		Paper	
e submitted						Other (Specify)	
Location of Net Contents  Label Co	Information ontainer	4. Size(s) R	etail Containe	er 5	On Lat	abel Directions bel beling accompa	
Manner in Which Label is	Affixed to Product	Par	ograph per glued nciled		Other		
			tion - IV				
Contact Point (Complete			of individual t	o be contact			
ame Stephen L. Longacre, Ph.D	Title		gistration Ma	nager	215 - 592	ne No. (Include:	Area Code)
certify that the statements I had acknowledge that any knowing both under applicable law.	Certific ave made on this form and	cation all attachments	s thereto are tr	ue, accurate a	nd complete.	6. Date Applic Received	
. Signature, 11		3. Title			•		•
Stephen h Lor	gar	Product Re	egistration Ma	nager		•••	
. Typed Name		5. Date					•

September 26, 2000

White - EPA File Copy (original)

Yellow Applicant Copy

Please read instructions on reverse before completing form.	Form Approved. OMB No. 20	70-0060
SEPA Environmental Protect Washington, DC	tion Agency Amenda	
Applica	tion for Pesticide - Section I	
1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
4. Company/Product (Name)	PM#	None Restricted
5. Name and Address of Applicant (Include ZIP Code)  Check if this is a new address	6. Expedited Review. In accordant (b)(i), my product is similar or identito:  EPA Reg. No  Product Name	
	Section - II	
Amendment - Explain below.  Resubmission in response to Agency letter dated  Notification - Explain below.  Explanation: Use additional page(s) if necessary. (For se	Final printed labels in response Agency letter dated "Me Too" Application.  Other - Explain below.	) to
	Section III	
1. Material This Product Will Be Packaged In:	Water Soluble Packaging 2. Type of	0
Child-Resistant Packaging  Yes  No  * Certification must  Unit Packaging  Yes  No  If "Yes" Unit Packaging wgt. contain	Yes No If "Yes" No per	Metal Plastic Glass Paper Other (Specify)
Label Container 4. Size(s)	Retail Container 5. Location of Lab	
<u> </u>	thograph Other	and a second and a second as a
	Section - IV	
1. Contact Point (Complete items directly below for identific		ocess this application.)
Neme	Title	Telephone No. (Include Area Code)
I certify that the statements I have made on this form	fication and all attachments thereto are true, accurate and cor statement may be punishable by fine or imprisonment	
2. Signature	3. Title	
4. Typed Name	5. Date	

#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send completing regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling:
- 5. Three copies of any date submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mookup of the proposed label. If prepared for mookup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mookup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Date submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION | - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing eddress of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter dete if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.

  Indicate the size of the individual packets and number per reteil container.
- 2. Type of Reteil Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to reteil container.

<u>SECTION IV</u> (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explenatory.
- 6. EPA Use Only.

Please read instructions on reverse before completing form.	Form Approx	red. OMB No. 2070-0060		
United States		Registration	-OPP Identifier Number	
Environmental Protection	Agency	Amendment	The state of the s	
Washington, DC 20460	- geney		277897	
Washington, DC 20460 Other				
Application for Pesticide - Section I				
1. Company/Product Number	2. EPA Product Manag	jer 3. Pi	roposed Classification	
4. Company/Product (Name)	PM#		None Restricted	
4. Company/r roduct (runte)				
5. Name and Address of Applicant (Include ZIP Code)	6 Expedited Student In control of FIFDA Costion 2/o1/21			
o. Hairs and Address of Applicant (archibe 21/ 6009)	6. Expedited Réview. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling			
	to:			
	EPA Reg. No.			
	al A riogi rio;			
Check if this is a new address	Product Name			
	Section - II			
Amendment - Explain below.	Amendment - Explain below. Final printed labels in response to			
Resubmission in response to Agency letter dated Agency letter dated "Me Too" Application.				
	Masdon at leashouse to Marky letter dates Into Loo Application			
Notification - Explain below.	Other - Expla	in belów.		
Employed on the callet at the same of the	-1 0 (II )	/		
Explanation: Use additional page(s) if necessary. (For section 1 at	na Section II.)			
			Market Street, St.	
	1			
	Section - III			
	Section - III			
1. Material This Product Will Be Packaged In:				
	Vater Soluble Packaging	2. Type of Container		
Yes Yes	Yes	Metel		
No No	No	Glass	of Allerton and Table	
	"Yes" No per	Paper		
Submitted Unit Packaging wgt. container	ackage wgt container	Other (	Specify)	
5. Location of Net Contents Information 4. Size(s) Retail Container 5. Location of Label Directions				
Label Container On Labeling accompanying product				
6. Manner in Which Label is Affixed to Product / Lithograph Other				
Paper glued Stenciled				
	Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
		\ \ \		
Name	•	I elephoi	ne No. (Include Area Code)	
/			<del></del>	
Certification 6. Date Application				
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.				
I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or (Stamped) both under applicable law.				
	Talo			
2. Signature 3. T	ine			
4 Tarabhara			-	
4. Typed Name 5. C	/616			
Account to the second s				

#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send completes regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use raregistration, amandment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Deta (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling:
- 5. Three copies of any date submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

-1

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reragistration actions, resubmissions, notifications, reregistrations, atc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate ection for which you ere submitting this form.

SECTION | - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Spacify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name end Address of Applicant The name of the firm or person end eddress shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to emend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of eubmission - Check the applicable block end provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, past or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

<u>SECTION III</u> (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Check the appropriete block if your product will be packaged in the indicated packaging types.

  Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Conteiner Specify the net contants of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is etteched to retail container.

SECTION IV (Contact Point) - This Section must be completed for all epplications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

ROHM

August 23, 2000

Wendy Sexsmith
Health Canada
Pest Management Regulatory Agency
2250 Riverside Drive, P.L. 6605E
Ottawa, Ontario K1A 0K9
Canada

SLL-00-198

Janet Anderson
U.S. Environmental Protection Agency
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Ms. Sexsmith and Ms. Anderson:

Subject: 1-Methylcyclopropene (1-MCP) EPA Discussions

This letter grants authorization for PMRA and EPA personnel to discuss matters and review documents regarding all applications to register Rohm and Haas owned 1-MCP products, including discussions regarding confidential business information, and for EPA to release written documents and reviews to PMRA, including those containing confidential business information.

Please telephone me at 215-592-3581 if you have any questions about this letter.

Sincerely,

Stephen L. Longacre, Ph.D.
Product Registration Manager
Agricultural Chemicals Registration

St Langue

and Regulatory Affairs Department

cc: Peter MacLeod (Rohm and Haas Canada)
Bob Larkin (Rohm and Haas US)
Sheryl Reilly (EPA BPPD)
Driss Benmhend (EPA BPPD)

#### DRAFT

May 9, 2000

Mr. Driss Benmhend
Biopesticides & Pollution Prevention Division
Office of Pesticide Programs (7511C)
U.S. Environmental Protection Agency
Room 902, Crystal Mall #2
1921Jefferson Davis Highway
Arlington, VA 22202

SLL-00-113

Dear Mr. Benmhend:

Subjects: Major Points and Follow-Up Actions from our 04May00 Meeting on:

Rohm and Haas Company's / BioTechnologies for Horticulture, Inc.'s (BTH's) Label Amendment to Add Food Crops to the Current Label for EthylBloc® Technology (EPA Reg. No. 71297-1), and

Rohm and Haas Company's / BTH's Petition for an Exemption from the Requirement of Tolerances for Residues of 1-Methylcyclopropene

(1-MCP) on Food Commodities

I would like to again thank you and your colleagues for meeting with us to discuss our recently submitted EthylBloc technology food-use petition, and our petition for an exemption from the requirement of tolerances for residues of 1-MCP (the active ingredient of EthylBloc) on food commodities. My understanding of the major points we discussed and agreed-upon follow-up actions are indicated below:

### Participants:

EPA BPPD:

Driss Benmhend Sheryl Reilly Russell Jones Freshteh Toghrol Rohm and Haas Company: Stephen Longacre

George Hazelton

### Clarification of EthylBloc Technology Ownership:

EthylBloc, a solid end-use product which contains 0.14% 1-MCP active ingredient, was registered for non-food use on flowers and related materials in April, 1999 (EPA Reg. No. 71297-1) by BioTechnologies for Horticulture, Inc. (BTH), a subsidiary of Floralife, Inc. (Walterboro, SC). Floralife, Inc. utilized Technology Sciences

Group (Amy Roberts, et al) as their regulatory consultant.

Mr. Benmhend 09May00 Page 2

Rohm and Haas Company purchased BTH from Floralife, Inc. in December, 1999. BTH is now a fully-owned subsidiary of the Rohm and Haas Company, and owns the EthylBloc registration and all data supporting the registration. Rohm and Haas Company has subregistered Floralife, Inc. the use of EthylBloc on flowers in the U.S.

Rohm and Haas Company/BTH now wishes to register EthylBloc for indoor use on fruits and vegetables post-harvest, and we submitted our food-use registration petition on April 6, 2000.

### Rohm and Haas Company/BTH's April 6, 2000 EthylBloc Food-Use Submission:

Our strategy to register EthylBloc for use on fruits and vegetables post-harvest consists of amending the current EthylBloc non-food use registration (EPA Reg. No. 71297-1) to include a number of food crops, along with submitting a petition for an exemption from the requirement of tolerances for 1-MCP residues on food commodities, and requesting waivers for all of those studies that were waived for the EthylBloc non-food use registration.

The following documents were submitted in support of the EthylBloc food-use registration:

- 1) Petition binder containing Sections A-J, which includes a draft product label for commercial food use, and a draft master non-commercial label containing both the current flower and proposed food uses.
- 2) Petition for an exemption from the requirement of tolerances for residues of 1-MCP on food commodities; Rohm and Haas Report No. 00R-1012; 04Apr00;
- Rationale for waivers of study requirements for registration of 1-MCP use on postharvested fruits and vegetables; Rohm and Haas Report No. AGREG-00-02; 04Apr00; and
- 4) FQPA Notice of Filing for 1-MCP on post-harvest fruits and vegetables; Rohm and Haas Report No. AGREG-00-01.

Action: Rohm and Haas/BTH will send the FQPA notice of filing document (AGREG-00-01) to Driss Benmhend electronically.

Six (6) crops are indicated on the draft food use label in the 06Apr00 submission, with apples being the most important of the submitted crops. Although we have some efficacy data on many other crops, we will periodically submit groups of crops to add to the EthylBloc food-use label after we have conducted additional efficacy studies to

determine the appropriate use-directions.

Mr. Benmhend 09May00 Page 3

I have been informed that our EthylBloc food-use petition passed the Agency's PR 86-5 screen. MRID numbers were assigned to my cover letter (Longacre to Benmhend, SLL-00-094; 06Apr00; MRID 450896-00), and our FQPA Notice of Filing (document #4 above; MRID 450896-01). MRID numbers were evidently not assigned to our petition for an exemption from tolerances (document #2 above) nor to our rationale for study waivers document (document #3 above).

Action: EPA/BPPD will have MRID numbers assigned to our petition for an exemption from tolerances (Rohm and Haas Report 00R-1012), and our rationale for study waivers document (Rohm and Haas Report AGREG-00-02), and will inform Rohm and Haas of these MRID numbers.

Petition for Exemption from the Requirement of Tolerances for Residues of 1-MCP on Food Commodities:

George Hazelton presented our rationale for requesting an exemption from the requirement of tolerances for 1-MCP on food commodities as contained in the submitted petition document (Rohm and Haas Report 00R-1012). Our rationale was based on the Agency's previous approach to granting exemptions from tolerances for ethylene and other plant growth regulators. Our estimates of residues of 1-MCP found in foodstuffs following treatment with EthylBloc are predicted to be extremely low (0.004 - 0.4 ppb), below reasonable quantifiable concentrations. These estimated levels of 1-MCP residues are based on the conservative assumption that all ethylene receptors are occupied by 1-MCP, along with submitted exposure data that shows that most of the 1-MCP in the treatment chambers is present at its nominal levels in the air above the food during the entire 6-24 hr treatment period. In the extreme worst-case, if one assumed that all (100%) of the 1-MCP in the chamber was on the food, which is not possible given that most of the 1-MCP is measured in the storage room air, then only 9 ppb 1-MCP would be calculated to be in/on the apples. Ten (10) ppb is a difficult detection limit for residues on food commodities. Since there would be predicted negligible residues on food commodities, there would be negligible exposure to consumers, and thus negligible risk to consumers.

MCP was reasonable, but pointed out that EPA scientists outside of BPPD may review this petition and that they may or may not agree with our rationale. (We will morn the registration of 1-MCP from Treatment Chambers to Outside Air:

We discussed that EPA/BPPD would like documentation indicating how fast it

takes for 1-MCP to dissipate from a treatment chamber during the venting process, and how fast and to what levels 1-MCP is diluted in the outside air.

Action: Rohm and Haas will prepare and submit documentation addressing the above points in support of our EthylBloc food-use petition.

Mr. Benmhend

09May00

Page 4

# Rationale for Waivers from Study Requirements in Support of the EthylBloc Food-Use Petition:

Rohm and Haas/BTH feels that it is appropriate to use the existing product chemistry and toxicology studies that supported the EthylBloc flower-use registration to support the EthylBloc food-use registration as well. The current EthylBloc database consists of 1) product chemistry, 2) six-study acute toxicity package, and 3) three mutagenicity studies, along with the submitted petition for an exemption from tolerances and the submitted study waiver rationale document. Our submitted waiver document is basically a reiteration of the waiver arguments used to support the flower-use registration; namely, indoor use with low application rates of a non-toxic material into treatment rooms that need to be sealed during the treatment period for efficacy reasons, and significant personal protective equipment requirements on the product label. Food-use applications may actually result in less potential worker exposure than the current flower-use, since there are not as many different application scenarios for food (essentially only indoor treatment chambers) as there are on the current flower label (trucks, greenhouses, etc.). Also, it is likely that for food-use applications, 1-MCP will be released from EthylBloc using a remote application device.

# Timing of EthylBloc Food-Use Registration:

I indicated that, prior to commercialization, we will be conducting large 3+ month efficacy trials in apples in huge storage facilities (greater than 1000 square meters) beginning this September or October. Since these trials would be in compliance with the 10 acre research trial restriction, an Experimental Use Permit (EUP) would not be needed. However, we urgently requested that the EthylBloc food-use registration begranted before these trials were initiated for us to avoid having to destroy all of these treated apples, which would cost us around \$500,000 to \$1,000,000. EPA/BPPD indicated that they would not grant a temporary exemption from tolerances for these trials even if they were conducted under an EUP. We agreed that there were not that many additional documents that needed to be reviewed for the EthylBloc food-use registration above and beyond those already reviewed and accepted for the EthylBloc flower/non-food use registration. However, EPA/BPPD indicated that a food-use registration by this September is unlikely, but a registration before the end of the large commercial trials (December, 2000 to February, 2001) may be doable (no promises), as 9=12)months is EPA/BPPD's current typical review time. EPA/BPPD indicated we might hear back on the acceptance of our petition for an exemption from the requirement of tolerances for 1-MCP residues on food commodities, and our rationale for waivers from

A CONTRACTOR OF THE PARTY OF TH

examp.

The war or

293

study requirements within the next three months.

Action: Rohm and Haas/BTH requests EPA/BPPD to inform us as soon as possible regarding the acceptance of our exemption from tolerances and study waiver rationale petitions so we can discuss and/or prepare contingency plans.

Mr. Benmhend 09May00 Page 5

1

# Revised EthylBloc Flower Label:

The California Department of Pesticide Regulation (CDPR) has recommended changes to the EthylBloc flower label that more accurately indicates Rohm and Haas Company's current ownership of BTH and the subregistrant relationship between Floralife, Inc. and Rohm and Haas/BTH. EPA/BPPD agreed that we could submit a revised flower-use label with the recommended changes (revised Registration Number, revised Floralife, Inc. Establishment Number, etc), along with a letter explaining the reasons for the modifications.

<u>Action</u>: Rohm and Haas/BTH will submit revised EthylBloc flower-use label and explanation letter.

# Registration Requirements for an Higher Containing 1-MCP Product:

I indicated that we foresee a need to manufacture and sell a formulation containing a higher amount of 1-MCP (i.e., a 1-5% 1-MCP product vs the current 0.14% 1-MCP product). The maximum treatment room exposure concentration of 1-MCP would remain at 1000 ppb v/v 1-MCP. EPA/BPPD indicated that this should be the subject of a separate meeting after they have had a chance to review the current EthylBloc food-use petition.

Please let me know if I have overlooked something or have not accurately captured any key points or action items. I can be reached by phone (215-592-3581), fax (215-592-3414), or Email (rstysl@rohmhaas.com) if you have any questions.

Sincerely,

Stephen L. Longacre, Ph.D.
Product Registration Manager
Agricultural Chemicals Registration

# and Regulatory Affairs Department

cc: Sheryl Reilly (EPA/BPPD)
Russell Jones (EPA/BPPD)
Freshteh Toghrol (EPA/BPPD)
George Hazelton (Rohm and Haas)

April 6, 2000

Mr. Driss Benmhend
Biochemical Pesticides Branch
US EPA Biopesticides and
Pollution Prevention Division (7511C)
Office of Pesticide Programs
1921 Jefferson Davis Highway, CM2
Arlington, VA 22202

SLL-00-094



Dear Mr. Benmhend:

Subjects: EthylBloc® Technology (EPA Regis. No. 71297-1)

Active Ingredient = 1-Methylcyclopropene

Label Amendment to Add Indoor Use on Post-Harvested Fruits

and Vegetables

Petition for Exemption from the Requirement of Tolerances for Residues of 1-Methylcyclopropene on Food Commodities

The attached petition from BioTechnologies for Horticulture, Inc., requests a label amendment to register EthylBloc (EPA Regis. No. 71297-1) for indoor use on post-harvest fruits and vegetables, and requests that the Agency establish an exemption from the requirement of permanent tolerances for 1-methylcyclopropene (1-MCP) residues on food commodities.

The solid end-use product, EthylBloc, which contains 0.14% 1-MCP active ingredient, is currently registered for non-food use on flowers and related materials (EPA Regis. No. 71297-1). 1-MCP has been classified by EPA as a plant growth regulator structurally similar to ethylene and other naturally occurring plant materials, and eligible for a reduced data set requirement. 1-MCP is regulated by the Biopesticides and Pollution Prevention Division (BPPD) of EPA.

Rohm and Haas Company purchased BioTechnologies for Horticulture, Inc. from Floralife, Inc., in December, 1999, and subregistered Floralife, Inc., the use of EthylBloc on flowers at that time. We now wish to register EthylBloc for use on fruits and vegetables after harvest as well.

This petition requests the establishment of an Exemption from the Requirement of Permanent Tolerances of 1-MCP residues on the raw agricultural food commodities. Our rationale for this request is contained in a document submitted with this petition (Hazelton, 2000), and is based on 1-MCP's non-toxic mode of action, its low use rates, its similarity in structure to naturally occurring plant growth regulators and plant materials, its gaseous form at room temperature, and the predicted low residues on treated food below reasonable analytical detection limits.

Pet. Ma?

# **Conditions of First Registration:**

All data required to satisfy the conditions imposed at the time of the first registration for EthylBloc (22Apr99) have been submitted. A reduced toxicology data

Mr. Benmhend 06Apr00 Page 2

set, along with waiver justifications, were required for the initial registration. Based on several meetings with EPA BPPD over the past several years, it is our understanding that EPA BPPD would require an FQPA notice of filing, a petition describing the rationale for an exemption from the requirement of tolerances for 1-MCP residues on food commodities, exposure/dissipation measurements during the use of 1-MCP, and waiver justifications for the remaining Tier 1 study requirements to support an indoor food use registration. Documents containing all of this additional information are included in this submission.

# Sections A (Product Chemistry) and B (Label Instructions):

Reviews of all studies required for this indoor food use petition were completed in conjunction with the earlier petition for use of EthylBloc on flowers.

A proposed post-harvest fruit and vegetable commercial use label, and a proposed master (non-commercial) combined flower and post-harvest fruit and vegetable use label for EthylBloc are submitted with this petition.

We are not aware of any other outstanding data requirement in these disciplines which is unique for indoor use on food commodities, and all data requirements for registration have been satisfied.

# Section C (Toxicology):

A reduced data set, along with waiver requests, were required for the initial non-food registration. Waiver justifications for subchronic toxicity and teratology studies are contained in this petition, and are also contained in a document submitted with this petition (Longacre, 2000).

We are not aware of any other outstanding data requirement in these disciplines which is unique for indoor use on food commodities, and all data requirements for registration have been satisfied.

# Sections D (Residue Chemistry) and F (Proposed Exemption from Tolerances):

1-MCP counteracts the effects of ethylene by binding to ethylene receptors in plants. Based on the number of ethylene receptors in apples and tomatoes and the low use levels, predicted 1-MCP residues would be below 1 ppb, which are below reasonable detection limits. A petition for an exemption from the requirement of tolerances for 1-MCP residues on food commodities based on 1-MCP's non-toxic mode of action, its low use rates, its similarity in structure to naturally occurring plant growth regulators and plant materials, its gaseous form at room temperature, and its predicted low residues on treated food below analytical detection limits, is included with this petition (Hazelton, 2000).

Mr. Bemnhend 06Apr00 Page 3

# Sections I (Ecological Effects) and J (Environmental Fate):

Waiver justifications for ecotoxicology and environmental fate studies for this proposed indoor use of EthylBloc are included with this petition, and are contained in a separate document submitted with this petition (Longacre, 2000).

#### Additional Items:

An FQPA Notice of Filing for 1-MCP on post-harvest fruit and vegetables is included with this petition, and was recently submitted to you electronically. It is our conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to I-MCP residues to the US population, including infants and children.

A tolerance fee of \$12,550, as specified in the 1999 EPA tolerance fee schedule for an exemption from the requirement of a tolerance [Federal Register, 64 (101); 26May99; p 28386; Sec 180.33(c)], was recently sent to EPA's Headquarters Accounting Operations Branch in support of this petition. A copy of my letter and a copy of the check are attached.

Since we are planning large Indoor long-term food storage trials with EthyiBloc beginning in late summer or early autumn, 2000, we request that the EthylBloc indoor food-use Section 3 registration be reviewed and granted before then to avoid a crop-destruct requirement for these large scale studies. If the Section 3 food-use registration cannot be granted by August, 2000, then we request a meeting to discuss provisions for an Experimental Use Permit by August, 2000 to avoid a crop-destruct requirement for the upcoming large trials.

Please assign MRID numbers to the new reports submitted in support of this petition, and please contact me by phone (215-592-3581), fax (215-592-3414), or E-mail (rstysl@rohmhaas.com) if you have any questions about this submission.

Sincerely.

Stephen L. Longacre, Ph.D. Product Registration Manager

Agricultural Chemicals Registration and Regulatory Affairs Department

CC:

Cheryl Reilly EPA BPPD

Robert Larkin Rohm and Haas Company Mr. Driss Benmhend 06Apr00 Page 4

# Attachments (reports in triplicate):

Guideline Reference	Rohm and Haas Company Report	Donort Title	MPID
Number PR Notice 97-1	Number AGREG-00-01	Report Title  1-Methylcyclopropene on Post-Harvest Fruits and Vegetables; An Assessment of the Risk Criteria Established in the Food Quality Protection Act (FQPA) Supporting an Exemption from the Requirement of Tolerances for BioTechnologies for Horticulture, Inc. Pesticide Petition Unassigned (1- Methylcyclopropene on Post-Harvest Fruits and Vegetables); 05Apr00	MRID
None Applicable	AGREG-00-02	S. L. Longacre; Rationale for Waivers of Study Requirements for Registration of 1-Methylcyclopropene Use on Post- Harvested Fruits and Vegetables; 04Apr00	
None Applicable	Rohm and Haas Report 00R-1012	G. A. Hazelton; Petition for an Exemption from the Requirement of Tolerances for Residues of 1-Methylcyclopropene on Food Commodities; 04Apr00	

#### Administrative materials submitted with this letter:

- 1) EPA Form 8570-1 (OPP Identifier 267635);
- 2) Petition binder containing Sections A, B, C, D, E, F, G, I and J; plus Data Matrix Tables (new and previously submitted studies);
- 3) EPA Form 8570-34: Certification with Respect to Citation of Data;
- 4) Copy of my 06Apr00 letter (SLL-00-095) to EPA Accounting Operations Branch Headquarters plus copy of tolerance fee check; and
- 5) Proposed Labels for 71297-1 (Post-Harvest Fruits and Vegetables; BO 4/5/00) and 71297-1 (Master Flower and Post-Harvest Fruits and Vegetables; MO 4/5/00) (5 copies each).

SPA E	United States  Invironmental Protection  Washington, DC 2046		X	Amendm Other		267630 271493
	Application for	or Pesticide - S	ection	1		
1. Company/Product Number		2. EPA Product	Manage	r	3. F	Proposed Classification
71297-1		Driss Benmhe	end			
4. Company/Product (Name)		PM#				None D Bestricter
EthylBloc®			9	2	×	None Restricted
5. Name and Address of App BioTechnologies for Hortin 100 Independence Mall W Philadelphia, PA 19106-2	culture, Inc. /est	(b)(l), my producto: EPA Reg. No	t is simil	ar or identica 538-256	ıl in coı	FIFRA Section 3(c)(3) mposition and labeling le XI (Fertilizer + Golden
	S	ection - II		<del></del>		
Notification - Explain be Explanation: Label amendm	nent to adjust 1-methylcycloproper t on product label from 99.89% to	99.86%, plus revised	plain belo	ow.		
		ection - III				
1. Material This Product William Child-Resistant Packaging Yes* No * Certification must be submitted	Unit Packaging Yes No  If "Yes" No. per Unit Packaging wgt.		aging	2. Type of	Metal Plastic Glass Paper	
3. Location of Net Contents Label Co.	nformation 4. Size(s)	) Retail Container	5.	Location of On La On La	bel	Directions accompanying product
6. Manner in Which Label is	F	Lithograph Paper glued Stenciled	] 0	ther		
	S	ection - IV				
. Contact Point (Complete in	tems directly below for identification		ontacted			
Name	Title Broduct I	Dogistration M.		Telepho	ne No.	(Include Area Code)
	Certification ve made on this form and all attachment may large false or misleading statement may				6. Da	te Application

3. Title

Date

March 8, 2000

Product Registration Manager

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

2. Signature

Typed Name

Stephen L. Longacre, Ph.D.

White - EPA File Copy (original)

Yellow - Applicant Copy

Form	Approved.	OMP No	2070-0060	n
1 911111	Appioved.	CIVID NO.	20/0-000	u

# United States

**Environmental Protection Agency** 

Registration
Amendment
Other

**OPP Identifier Number** 

	Washingt	ton, DC 20460			Other		211493
	A	pplication	for Pestici	de - Sectio	n I		
1. Company/Product Number			2. EPA	Product Manage	r	3. Prop	posed Classification
4. Company/Product (Name)			PM#			10	None Restricted
4. Company/Product (Name)			FIMIN				
5. Name and Address of App	plicant (Include ZIP Code		(b)(i), n to: EPA F				FIFRA Section 3(c)(3) position and labeling
			Section -			/	
Amendment - Explain  Resubmission in resp  Notification - Explain  Explanation: Use addition	conse to Agency letter de		end Section II.)	Final printed ia Agency letter o "Me Too" App Other - Explain	lication	0	
			Section - I	11			
1. Material This Product Wil	Be Packaged In:						
Child-Resistant Packaging Yes* No Pertification must submitted	Ves No If "Yes" Unit Packaging wgt.	No. pg	Water Soluble F Yes No If "Yes" Paokage wgt	No. per container		ontainer Metal Plastic Glass Paper Other (Sp	esify)
3. Location of Net Contents	Information Container	. Size(s) Reteil	Container	5.	On Labelin		enying product
6. Manner in Which Lebel is	Affixed to Product	Lithograp Paper glu Stenciled		Other			
			Section - I				
1. Contact Point <i>(Complete</i> Name	items/directly below for	identification o		e contacted, if i			No. (Include Area Code)
	oments I have made on the house of minimum.		attachments th			olete.	6. Date Application Received (Stamped)
2. Signature		3.	Title				
4. Typed Name		5.	Dats				201

#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send completing regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, information Policy Branch, (2136), U.S. Environmental Protection Agency; 401 M Street, SW, Weshington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to fecilitate storage in en 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Dats - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrent, a distributor, or as an astablishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be Issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA eaction 3 (a) 3 (b) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other posticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that partains to a specific EPA-registered product. This section is not to be used for a new application for registration.

Subject of submission - Check the applicable block and provide the Agency latter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, past or crop (specify)"; "amend the Confidential Statement of Formula by..."; "raregistration submission"; "general label revision of use directions." Attach a saparate page if additional space is needed.

SECTION III (Peckeging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Peckeging Check the appropriate block if your product will be peckeged in the indicated peckeging types.
   Indicate the size of the individual peckets and number per retail container.
- 2. Type of Retail Contelner Indicate type of container in which product will be merketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product,
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

<u>SECTION IV</u> (Contact Point) - This Section must be completed for all applications for Registration ections, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explenetory.
- 6. EPA Use Only.

1150	The same			
	United States Environmental Protection Washington, DC 204	on Agency	Registration Amendment Other	OPP Identifier Number 271,493,
	Application	on for Pesticide - Sec	tion I	
1. Company/Product Number		2. EPA Product Mar	ager 3. Pr	oposed Classification
4. Company/Product (Name)		PM#	7.0	None Restricted
5. Name and Address of App  Check if this	is a new address	(b)(i), my product to:	view. In accordance with is similar or identical in co	
		Section - II		
Amendment - Explain Resubmission in resp. Notification - Explain	onse to Agency letter deted	Agency let	d labels in response to ter dated Application:	
		Section - III		
1. Materiel This Product Will				
Child-Resistant Packaging Yes* No Pertification must submitted	Ves No  If "Yes" Unit Packaging wgt.  No. par Container	Water Soluble Packaging Yes No If "Yes" Package wgt No. per	2. Type of Container  Metal Plastic Glass Paper Other (	Specify)
3. Location of Net Contents	Information (4 Size(a) Re	otail Container	5. Location of Label Directi	one
	Container	.can containe	On Label On Labeling accord	
6. Manner in Which Label is	Affixed to Product Lithor Paper Stend	graph Other		
		Section - IV		
1. Contact Point (Complete	items directly below for identificati	on of individual to be contacted	, if necessary, to process this	s application.)
Name		Title	Telephoi	ne No. (include Area Code)
	Certific ments I have made on this form an by knowingly felse or misleading sta law.	d all attachments thereto are tru		6. Date Application Received (Stamped)
2. Signature		3. Title		

5. Dets

4. Typed Name

#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send completing regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20480.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling:
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Date - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please reed the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been essigned by EPA. This number may have been assigned to you as a basic registrent, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this posticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and eddress shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of enother party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing eddress of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

<u>SECTION II</u> - This section must be completed for all applications eubmitted to emend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a <u>specific EPA-registered product</u>. This section is <u>not to be</u> used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explenation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reragistration submission"; "general label ravision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.

  Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of conteiner in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Conteiner Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

<u>SECTION IV</u> (Contact Point) - This Section must be completed for all applications for Registration ections, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

B

ROHM

March 8, 2000

Mr. Driss Benmhend
Biochemical Pesticides Branch
US EPA Biopesticides and
Pollution Prevention Division (7511C)
Office of Pesticide Programs
1921 Jefferson Davis Highway, CM2
Arlington, VA 22202

SLL-00-074

Dear Mr. Benmhend:

Subject: EthylBloc® (EPA Regis. No. 71297-1)

Active Ingredient = 1-Methylcyclopropene

Revised Label Amendment to Adjust Active Ingredient

Content to 0.14%

Reference: Label Amendment Submitted 03Mar00 (SLL-00-068)

BioTechnologies for Horticulture, Inc. submits the attached revised label amendment to indicate an adjustment in the nominal content of the active ingredient 1-methylcyclopropene (1-MCP) in the registered end-use formulation EthylBloc (EPA Regis. No. 71297-1) to 0.14% from the 0.11% indicated in our 03Mar00 label amendment submission. Revised Confidential Statements of Formula for both the basic and alternate formulations of EthylBloc reflecting the adjustment to 0.14% 1-MCP in the EthylBloc formulation are also attached.

EthylBloc was registered for use on flowers in April, 1999 by BioTechnologies for Horticulture, Inc. (BTH). Rohm and Haas purchased BTH in December, 1999, and subregistered Floralife Inc. (Walterboro, SC) the use of EthylBloc on flowers at that time.

My 03Mar00 label amendment indicated that we recently discovered that the actual 1-MCP ai content of the EthylBloc end-use formulation was about one-fourth of the 0.43% ai content indicated on the product label. I indicated that the decreased ai content was <u>not</u> due to any significant change in the manufacturing process, but that it was due to a less rigorous analytical procedure used by Floralife over the past several years. My 03Mar00 label amendment specified the nominal 1-MCP content as 0.11% in EthylBloc end-use product.

We quantify 1-MCP in EthylBloc end-use product by gas chromatography using a flame ionization detector, and using isobutylene as an internal standard. An aliquot of EthylBloc end-use product is dissolved in buffer solution in a sealed vial, and after equilibration, a sample of the headspace gas is analyzed.

Mr. Benmhend 08Mar00 Page 2

The 0.11% ai nominal concentration was determined using an injection port temperature of 250 deg C during the gas chromatographic analysis. Earlier this week, after I had submitted by 03Mar00 label amendment to the Agency, our researchers conducted additional analyses of 1-MCP in EthylBloc using an injection port temperature of 150 deg C in an attempt to reduce a small amount of an apparent degradation product observed in the analysis. Quantitation of 1-MCP in EthylBloc using the reduced injection port temperature of 150 deg C revealed a nominal 1-MCP concentration of 0.14% in the EthylBloc formulation. This slightly greater amount of nominal 1-MCP in the EthylBloc formulation (0.14% vs 0.11%) is likely due to less degradation in the injection port at 150 deg C versus 250 deg C. The only difference in the analyses was the injection port temperature. We now believe 0.14% is the accurate nominal concentration of 1-MCP in the EthylBloc formulation; thus the reason for submitting this revised label amendment.

As I indicated in my 03Mar00 label amendment submission, Floralife, who currently manufactures and sells EthylBloc, stopped production last week when we became aware of this lower ai issue. However, Floralife is a small company and needs to resume production as soon as possible or face significant economic hardship.

Anything that the Agency can do to expedite approval of this revised label amendment so that Floralife may resume production of EthylBloc by the end of this week would be greatly appreciated.

Please contact me by phone (215-592-3581), fax (215-592-3414), or E-mail (rstysl@rohmhaas.com) if you have any questions about this label amendment.

Sincerely.

Stephen L. Longacre, Ph.D. Product Registration Manager

St Longane

Agricultural Chemicais Registration and Regulatory Affairs Department

Mr. Benmhend 08Mar00 Page 3

Administrative materials submitted with this letter:

- 1) EPA Form 8570-1 (OPP Identifier 267630);
- 2) Revised Product Label for 71297-1 (SLL/08Mar00) (5 copies)
- 3) Revised Confidential Statement of Formula / Basic Formulation (dated 08Mar00); and
- 4) Revised Confidential Statement of Formula / Alternate Formulation (dated 08Mar00).

307

#### HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION, Causes moderate eve irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid breathing vapors. Wash thoroughly with scep and water after handling. Remove contaminated clothing and wash before rause. STORAGE Store in original packaging in a cool, dry place.

Active Ingredient (1-Methylcyclopropene) ..... 100.00%

#### KEEP OUT OF REACH OF CHILDREN CAUTION

Refer to insert label for additional precautionary statements and directions for use.

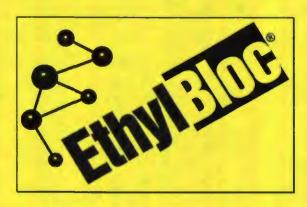


is a powder that when mixed with water or a buffer solution. releases a gas to extend the life and usefulness of many fresh cut flowers, potted flowering, bedding, nursery and foliage plants. Crops are treated with this gas in enclosed areas such as rooms, coolers, greenhouses, truck trailers and shipping boxes/containers. This product is not intended for use only on ornamental, non-food crops Do not use

outdoors or in other non enclosed areas EPA Registration No. 71297-1 EPA Establishment, No. 71297-8C-00

**NET CONTENT:** 100 grams





EthylBloc<sup>®</sup> is a powder that, when mixed with a Mixing/Buffer solution or water, releases a gas to extend the life and usefulness of many fresh cut flowers, potted flowers, bedding, nursery and foliage plants. Plants are treated with this gas in enclosed areas such as rooms, coolers, greenhouses, truck trailers and shipping boxes/containers. This product is intended for use only on ornamental, non-food crops. Do not use outdoors or in other non-enclosed areas.

 Active Ingredient:
 1-Methylcyclopropene
 00.14%

 Other Ingredients:
 99.86%

 Total:
 100.00%

# CAUTION KEEP OUT OF REACH OF CHILDREN

#### Statement of Practical Treatment

IF IN EYES: Flush with plenty of water. Call a physician if irritation persists. IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration,

preferably mouth-to-mouth. Get medical attention.

Refer to Insert label for additional Precautionary Statements and Directions for Use.

Manufactured by: Floralife, Inc.

751 Thunderbolt Drive Walterboro, SC 29488 www.floralife.com

For product Information, call toll-free (800) 323-3689 or (843) 538-3839

EPA Registration No.: 71297-1

EPA Establishment No.: 71297-SC-001

U.S. Patent No. 5,518,988

Net Contents: 38 g (water soluble packet), 75 g (water soluble packet), 100 g bottle.

# PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS



Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and mixers of this product must wear:

- >Long-sleeved shirt and long pants.
- >Shoes plus socks.
- >Protective evewear (goggles or face shield).
- >Rubber gloves.
- >As a general precaution when exposed to gas, for activities in enclosed areas wear a respirator with either an organic vapor-removing cartridge with a pre-filter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G).
- >Applicators and handlers must follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

# **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in original packaging in a cool, dry place.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

EthylBloc® can extend the life and usefulness of many fresh cut flowers and potted flowers, bedding, nursery and foliage plants. It works by inhibiting the negative effects of ethylene and thus prevents or reduces premature flower death, leaf and/or flower fall, and leaf yellowing.

EthylBloc® is specifically designed to be used by all levels of the floral and nursery Industries, including growers, shippers, wholesalers, bouquet manufacturers, mail-order houses and retailers (such as florists, garden centers, nurseries and mass-market outlets). EthylBloc® is very easy to use with almost no labor costs.

EthylBloc® can be used just prior to harvest, immediately after harvest, just prior to shipment, upon arrival from the supplier, and/or just prior to sale. It comes with two scoops for easy measuring and the proper Mixing/Buffer Solution. EthylBloc® is in a water soluble package for easy use with the proper Buffer (mixing) solution. The Mixing/Buffer Solution is used to facilitate gas release. Users can substitute tap water for the Mixing/Buffer Solution but the gas release will not be as efficient. Contact the manufacturer for specific directions. EthylBloc® is more effective under warm temperature conditions, 55° to 75°F, (13° to 24°C). Longer treatment times are required for plants held under temperatures below 55°F, (13°C).

#### **FLOWERS AND PLANTS**

EthylBloc® treatment benefits many flowers and plants such as:

Achillea	Celosia	Freesia	Phlox
Aconitum	Centaurea	Fuchsia	Physostegla
Agapanthus	Chamaedorea	Geranlum	Polnsettia
Alchemilla	Chelone	Gladiolus	Radermachera
Allium	Coleus	Godetia	Rose
Alstroemeria	Cordyline	Gypsophila	Rudbeckia
Alyssum	Cymbidium	Hibiscus	Salvia
Aphelandra	Crocosmia(Montbretia)	Ilex (Holly)	Saponaria
Aquilegia	Daucus (Queen Annes	Impatiens	Scabiosa
Asclepias	Lace)	Ixia	Silene
Astrantia	Delphinium	Kalanchoe	Snapdragon
Asparagus Fern	Dendroblum	Kniphofla	Solidaster
Azalea	Dianthus	Lavatera	Stock
Begonia	Dicentra	Lily	Streptocarpus
Bouvardia	Dizygotheca	Lysimachia	Sweet William
Brassaia (Schefflera)	Doronicum	Miniature Carnation	Trachelium
Brodiaea (Tritelela)	Echium	Monkshood	Trollius
Calathea	Eremurus	Peiargonium	Veronica
Campanula	Eustoma (Lisianthus)	Petunia	Wax Flower
Carnation	Ficus	Philodendron	Zygocactus

To realize maximum benefits, plants should be treated whether or not they may have been previously treated with EthylBloc® or another anti-ethylene product. Shipments already treated with EthylBloc® do not have to be retreated, however, retreating is not harmful and can even be beneficial. Some species that would likely benefit from additional applications include those with more than one flower per stem (i.e., snapdragons, delphiniums, miniature carnations and alstroemeria) and flowers at different stages of development on the same plant (i.e., geraniums, impatiens, and azaleas).

# TREATMENT INSTRUCTIONS

- Calculate the treatment volume by measuring the length, width and height of the treatment area In
  feet or meters. Multiply these three numbers together to obtain the volume of the room/area In
  cubic feet or cubic meters. For example, if a room is 4 feet wide, 5 feet long and 5 feet high, the
  volume equals 100 cubic feet.
- 2. Wear all Personal Protective Equipment (PPE) required under Precautionary Statements.
- 3. Use a plastic mixing container large enough to hold the EthylBloc® and Mixing/Buffer Solution. A plastic pail works well for larger applications, a plastic bowl or similar container for smaller applications.
- 4. First add Mixing/Buffer Solution to the mixing container. Then add the EthylBloc® powder. The amounts of EthylBloc® and Mixing/Buffer Solution are specified in the following tables/boxes. For water soluble packets, first add Mixing/Buffer Solution to the mixing container. Then add the water soluble packet of EthylBloc® to the mixing container, making sure the water soluble packet is covered. The amounts of EthylBloc® and Mixing/Buffer Solution are specified in the following tables/boxes.

- 5. Following the addition of EthylBloc<sup>®</sup> to the Mixing/Buffer Solution, leave the treatment area immediately. Make sure the area is sufficiently sealed. See following application sections for details.
- 6. POSTING: Signs should be posted on all potential entry points during EthylBloc® treatment (for at least four hours or as otherwise recommended in the Directions for Use). Signs should state "CAUTION! Do not enter area. EthylBloc® treatment underway." Posting is suggested as a means of ensuring optimal effectiveness of EthylBloc®.
- 7. After the treatment period ends (see below tables/boxes for specified treatment periods), ventilate treated areas with outside air before re-entry.
- 8. Remaining treatment solution can be disposed of on site or at an approved waste disposal facility.

#### SPECIFIC TREATMENT PERIODS

TREATMENT CONDITIONS: 55 to 75 F, 4 to 8 hours

TREATMENT RATE: 1.5 gram of EthylBloc® plus 1 fl. oz. Mixing Solution per 100 cubic feet

Amount of EthylBloc®	Amount of Mixing Solution	<b>Cubic Feet to Treat</b>
1 White Scoop	1 tsp	13
1 Green Scoop	2 Tosp	100
38 g Water Soluble Packet	25 fl oz or 3 cups plus 2 Tbsp	2500
75 g Water Soluble Packet	50 fl oz or 6 cups plus 4 Tbsp	5000

METRIC FOUTVALENT

Amount of EthylBloc®	Amount of Mixing Solution	Cubic Meters to Treat
1 White Scoop	5 ml	0.4
1 Green Scoop	30 ml	3
38 g Water Soluble Packet	750 ml	75
75 g Water Soluble Packet	1500 ml	150

#### TREATMENT CONDITIONS: 55 to 75 F, minimum 10 hours

TREATMENT RATE: 1.5 gram of EthylBloc® plus 1 fl. oz. Mixing Solution per 200 cubic feet

Amount of EthylBloc®	Amount of Mixing Solution	Cubic Feet to Treat
1 White Scoop	1 tsp	26
1 Green Scoop	2 Tosp	200
38 g Water Soluble Packet	25 fl oz or 3 cups plus 2 Tbsp	5000
75 g Water Soluble Packet	50 fl oz or 6 cups plus 4 Tbsp	10000

METRIC EQUIVALENT

Amount of EthylBloc®	Amount of Mixing Solution	Cubic Meters to Treat	
1 White Scoop	5 ml	0.8	
1 Green Scoop	30 ml	6	
38 g Water Soluble Packet	750 ml	150	
75 g Water Soluble Packet	1500 ml	300	

#### TREATMENT CONDITIONS: 35 to 55 F, minimum 10 hours

TREATMENT RATE: 1.5 gram of EthylBloc® plus 1 fl. oz. Mixing Solution per 100 cubic feet

Amount of EthylBloc®	Amount of Mixing Solution	Cubic Feet to Treat
1 White Scoop	1.5 tsp	13
1 Green Scoop	3 Tbsp	100
38 g Water Soluble Packet	37 fl oz <u>or</u> 4 2/3 cups	2500
75 g Water Soluble Packet	75 fl oz <u>or</u> 9 1/3 cups	5000

METRIC EQUIVALENT

Amount of EthylBloc®	Amount of Mixing Solution	Cubic Meters to Treat
1 White Scoop	7 ml	0.4
1 Green Scoop	45 ml	3
38 g Water Soluble Packet	1125 ml	75
75 g Water Soluble Packet	2250 ml	150

Measurements: WHITE SCOOP = 0.2 grams EthylBloc® powder GREEN SCOOP = 1.5 grams EthylBloc® powder

1 teaspoon = 1 tsp = 5 ml

1 Tablespoon = 1 Tbsp = 3 tsp = 1/2 fl oz

1 fl oz = 2 Tbsp. = 30 ml1 cup = 8 fl oz = 240 mi

38 gram Water Soluble Packet will treat a 20 ft truck container 75 gram Water Soluble Packet will treat a 40 ft truck container

> EthylBloc® Last label revision, March 9, 2000 - Label redesign Page 5 of 7

#### **APPLICATION IN GREENHOUSES PRIOR TO HARVEST**

Fresh cut flowers and bedding, potted flowering, nursery and foliage plants can be treated in the greenhouse just prior to being harvested.

- 1. The greenhouse must be tightly constructed. Plastic covered houses (especially "double-poly") are generally tighter than fiberglass or glass covered ones.
- 2. Sections of greenhouses can be enclosed with plastic to make the treatment area smaller, as long as it is sealed sufficiently to prevent the gas from escaping. Excessive leakage reduces effectiveness of EthylBloc<sup>®</sup>.
- 3. Make sure all greenhouse vents are closed. Night treatment is recommended mainly because vent closing is more realistic and treatment times can be longer.
- 4. Any internal air circulation system (that does not bring in outside air) should remain on during treatment to help distribute the gas.
- 5. All greenhouse treatments should be done at temperatures greater than 55° F (13°C).
- 6. When calculating treatment volumes, use ½ of the height measured at the ridge/peak for the height measurement. If a greenhouse is 25 feet wide, 100 feet long and 10 feet high, the approximate volume equals 25 x 100 x 10/2 = 12,500 cubic feet.
- 7. Follow steps under Treatment Instructions.

# APPLICATION IN ENCLOSED AREAS SUCH AS: HOLDING/STORAGE ROOMS, COOLERS, AND TRUCK TRAILERS

Plants being held in enclosed areas can be easily treated with EthylBloc®. For example, non-boxed sleeved potted plants and cut flowers (held dry or in solution), or boxed plants and cut flowers with the lids and/or pre-cooling vents completely open and directly exposed to the surrounding atmosphere can be treated. Bedding or potted plants on movable racks are also easily treated.

#### Typical treatment areas

- Retail and wholesale florist coolers including walk-in, storage and/or walk-in/storage combinations;
- Delivery trucks or vans, truck trailers, inter-modal containers, regardless of their size/volume;
- Any room in a building that can be isolated, sealed and aerated/vented to the outside after treatment.
- 1. Treatment areas should be checked for gas leakage. Excessive leakage reduces effectiveness of EthylBloc®.
- 2. If needed, use plastic liners, tape and/or other products and procedures to make enclosed areas more gas/air tight.
- 3. Any internal air circulation system (that does not bring in outside air) should remain on during treatment to help distribute the gas.
- 4. Temperatures should be between 35° and 75° F (1.6° and 24° C).
- 5. Follow steps under Treatment Instructions.

# APPLICATION IN AREAS SPECIFICALLY BUILT FOR ETHYLBLOC® TREATMENT

General EthylBloc® Treatment Chamber. It might be appropriate to construct an area to be used solely for EthylBloc® treatment. Constructing such specific EthylBloc® treatment areas has proven to be an effective way of using EthylBloc®. This maximizes EthylBloc® effectiveness and reduces costs by requiring less product to treat a given number of plant units.

While this treatment area could be built using a number of gas impermeable materials, 4.0 to 6.0 mil polyethylene sheeting works well. Just make sure the units seals properly.

One way to help ensure a good seal where the plastic comes in contact with the flooring is to use hydration solution. The treatment unit base is submerged in a trough of hydration solution a few inches deep, thus making a good seal where gas cannot escape.

To use such a treatment area, follow the treatment instructions adjusting for treatment volume and temperatures.

**Cut Flower Hydration EthylBloc® Treatment Chamber.** The top of the chamber can be made of 4.0 to 6.0 mil polyethylene sheeting and a wooden frame, or a single plastic piece that can fit into the bottom hydration tank, or something similar. The bottom tank can be any size tub that is capable of holding hydration solution and flowers. See drawing below.

Top plastic tent. Should be made to fit into the bottom hydration tank.

Plastic Tent

EthylBloc® is released into the top plastic tent treating all of the flowers inside the tent.

Bottom tank is about 15-20 cm high and full of hydration solution. The flowers sit in this solution and hydrate while being treated with EthylBloc®.

Place the flowers in bunches or in buckets in the bottom tank. Place the top plastic tent over the bottom holding tank. The tent's bottom edges must be able to be submerged into the hydration solution in the bottom holding tank to insure a seal. Follow Treatment Instructions making sure the EthylBloc® mixture remains separate from the hydration solution throughout the treatment.

**WARRANTY.** BioTechnologies for Horticulture, Inc. warrants that this material conforms to the chemical description on the label. BioTechnologies for Horticulture, Inc. neither makes nor authorizes any agent or representative to make any other warranty of fitness or of merchantability, guarantee or representation, express or implied, concerning this material. The maximum liability for breach of this warranty shall not exceed the purchase price of this product. BioTechnologies for Horticulture, Inc.'s maximum liability for breach of this warranty shall not exceed the purchase price of the product. Buyer and user acknowledge and assume all risks and liabilities resulting from the handling, storage and use of this material, whether or not in accordance with directions.

Questions? Contact Floralife, Inc.
Toll-free (800) 538-3320 or call (843) 538-3839.

# **Environmental Protection Agency**

246808

Office of Pesticide Programs (7505C)

Washington, DC 20460

# Notice of Supplemental Distribution of a Registered Pesticide Product

#### Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product	Distributor Company Number	
671297-18	632258	
Note: Do not submi	t distributor product labels	
Name of Registered Product (basic product name accepted by EPA)	Distributor Product Name	
EthylBloc (R)	EthylBloc (R)	• • •
Name and Address of Distributor (Type; include ZIP code)		
Floralife, Inc. 751 Thunderbolt Dr.		
Walterboro, S.C. 29488		
war cerboro, 5,0, 25400		*****
Read All Conditions	Before Signing	• •••••
		••••
1. The distributor product must have the same compositi	The state of the s	••••
2. The distributor product must be manufactured and page	ckaged by the same person who man	ufactures and packages
the registered basic product.  3. The labeling for the distributor product must bear the	came claims as the basic product. pr	ovided however that
pecific claims may be deleted if by doing so, no other		, vided, flowever, that
4. The product must remain in the manufacturer's unbro		
<ol><li>The label must bear the EPA registration number of the company number.</li></ol>	e basic product, followed by a hyphe	n and the distributor's
6. Distributor product labels must bear the name and add	dress of the distributor qualified by su	ch terms as "packed
for", "distributed by"; or "sold by" to show that		
7. All conditions of the basic registration apply equally to		
registrant to see that all distributor labeling is kept in c	ompliance with requirements placed to	The basic product.
Distril		
We intend to market our product under the Distributor Product Name sp	ecified above, subject to the conditions specifi	ed on this Notice.
Signature and Title of Distributor	Date	e
by: Laws figtera	12/	15/99
Regis	strant	
I agree that the distributor named above may distribute and sell the Distribute.	tributor Product specified above, subject to the	conditions specified on this
Signature and Title of Registrant	0-	
Raber M. Xarkes	Da	
Riotecknologies for Horticulture	12/	15/99
EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete.	1.19	Mhite - FPA

# Paperwork Reduction Act Notice

The annual respondent burden for the Notice of Supplemental Distribution of a Registered Pesticide Product is estimated to average 15 minutes per response, including time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information. Send comments regarding this burden, to Director, Regulatory Information Division, 2137, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460; and to Paperwork Reduction Project (OMB No. 2070-0044), Office of Management and Budget, Washington, DC 20503, Marked "Attention Desk Officer for EPA.



# PESTICIDE FACT SHEET

Name of Chemical(s):

Methylcyclopropene

Reason for Issuance:

New Active Ingredient

Date Issued:

April, 1999

**EPA Publication Number:** 

# I. DESCRIPTION OF THE PESTICIDE

Generic Names of the Active Ingredient:

1-Methylcyclopropene (MCP)

**OPP Chemical Code:** 

224459

**Pesticide Types:** 

Plant Growth Regulator

**U.S. Registrants:** 

Biotechnologies for Horticulture, Inc.

751 Thunderbolt Road Walterboro, SC 29488

# II. <u>USE SITES, APPLICATION TIMING & TARGET PESTS</u>

**Target Pests:** 

Inhibit the Effect of Ethylene

**Use Sites:** 

MCP is to be used in confined areas to extend the life and usefulness of fresh cut flowers and potted flowering, bedding, nursery and foliage plants. Plants are treated in enclosed areas such as rooms, coolers, greenhouses, truck trailers and shipping boxes/containers. The use is classified as indoor

nonfood crops application.

**Application Timing:** 

Applications should be made just prior to harvest, immediately after harvest, prior to shipment, upon arrival from the supplier, and/or just prior to sale.

Repeat at weekly intervals.

# III. SCIENCE FINDINGS

# A. HUMAN HEALTH EFFECTS:

The information submitted in support of the application for registration of MCP adequately satisfies the requirements set forth in 40 CFR 158.690 (c) for biochemical pesticides for nonfood indoor uses. The overall toxicological risk from human exposure to MCP is considered negligible.

# 1. Toxicology Assessment

Adequate mammalian toxicology data are available and support registration of the active ingredient 1-Methylcyclopropene.

# a. Acute Toxicity

The registrant submitted acceptable acute toxicity studies. Based on a lack of mortality observed in albino rats orally dosed with 5000 mg/kg of powdered product, the oral  $LD_{50}$  was >5000 mg/kg; tox category IV. Based on a lack of mortality observed in albino rabbits dermally dosed with 2000 mg/kg of powdered product, the  $LD_{50}$  was >2000 mg/kg; tox category III. Based on a lack of mortality observed in albino rats exposed to 165 ppm of MCP gas for 4 hours, the  $LC_{50}$  was >165 ppm; tox category IV. Ocular instillation of 0.1 ml of powdered product caused mild to moderate eye irritation symptoms (redness, chemosis) which cleared by 72 hours posttreatment; tox category III. Dermal application of 0.5 g of powdered product did not cause any dermal irritation symptoms up to 72 hours postdosing; tox category IV. Based on the data, the test substance is not considered to be a contact sensitizer. No hypersensitivity incidents have been reported.

# b. Mutagenicity and Developmental Toxicity

The registrant submitted acceptable mammalian mutagenicity studies for MCP. Based on the data obtained from the Salmonella typhimurium microsome reverse mutation assay, MCP did not induce positive increases in the number of revertants. The data obtained from the mouse lymphoma forward mutation assay showed that MCP did not induce a significant increase in mutant cells relative to controls; no dose-response effects nor cell toxicity effects were observed. Based on the data obtained from the in vivo mouse microsomal assay, MCP did not induce increases in micronucleated PCEs (polychromatic erythrocytes) relative to vehicle controls; no bone marrow toxicity [measured as a decrease in PCE:NCE (normochromatic erythrocytes) ratio] was observed for any dose of test substance. Additionally, 4100 person hours of MCP exposure have been experienced by humans without any known MCP-induced health related problems being reported. Based on a lack of statistically significant data obtained from a reverse-mutation assay study a mouse lymphoma forward mutation study assay, and a mouse micronucleus study, MCP is not considered a mutagen. The information submitted in support of the application for registration of MCP adequately satisfies the requirements set forth in 40 CFR 158.690 (c) for biochemical pesticides for nonfood outdoor uses.

The overall toxicological risk from human exposure to MCP is considered negligible.

# c. Subchronic Toxicity

A 90 - day feeding study was not required because of the nonfood use of MCP. Moreover, the 90 - day dermal and inhalation toxicity studies are not required because the proposed use pattern does not result in prolonged exposure at concentrations that are likely to be toxic. The immunotoxicity study (cellular immune response study) was waived based on the minimal potential for exposure and the low toxicity of MCP shown in the studies submitted.

# d. Chronic Exposure and Oncogenicity Assessment

Chronic exposure studies are conditionally required to support nonfood uses only if the potential for adverse chronic effects are indicated based on 1) the subchronic effect levels established in Tier I subchronic oral, inhalation, or dermal studies, 2) the pesticide use pattern, or 3) the frequency and the level of repeated human exposure that is expected. Oncogenicity studies are required to support non-food uses only if the active ingredient or any of its metabolites, degradation products, or impurities produce in Tier I studies morphologic effects in any organ that potentially could lead to neoplastic changes. The triggers for chronic exposure and oncogenicity studies were not met.

# e. Effects on the Endocrine Systems

The agency is not requiring information on the endocrine effects of this compound at this time. Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects. However, BPPD has considered, among other relevant factors, available information concerning whether MCP has an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known evidence so far that the active ingredient act as an endocrine disruption in humans. No adverse effects to the endocrine system is known or expected.

# 2. Dose Response Assessment

No toxicological endpoints are identified.

#### 3. Dietary Exposure and Risk Characterization

Dietary exposure is unlikely to occur because of the nonfood use of MCP. In the absence of any toxicological endpoints, risk from the consumption of residues is not expected for the general population including infants and children.

# 4. Occupational, Residential, School and Day Care Exposure and Risk Characterization

Human exposure to MCP is not expected in these areas.

# a. Occupational Exposure

Based on its low toxicity and its use on ornamentals intended for aesthetic purposes, MCP is not subject to the Worker Protection Standards (WPS). Moreover, the possibility for dermal, eye and inhalation exposure, is mitigated as long as the product is used according to label directions which recommends the use of protective equipment by users, posting signs to keep people out of treated areas, and allowing proper ventilation time before permitting human activity in the treated areas.

# b. Residential, School and Day Care Exposure and Risk Characterization

No indoor residential, school, or day care uses currently appear on proposed labels.

# 5. Drinking Water Exposure

Exposure to MCP in drinking water is not expected.

# 6. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

There are no food uses associated with the proposed use of the MCP. Therefore, the acute dietary risks should be negligible based on the lack of exposure.

# 7. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

Aggregate exposure would primarily occur in the applicators subpopulations via dermal and inhalation routes. Risks associated with dermal and inhalation aggregate exposure are measured via the acute toxicity studies submitted to support registration. Because the inhalation toxicity studies for MCP showed no toxicity (Toxicity Category IV), the risks anticipated for this route of exposure are considered minimal. Results of the acute dermal study indicated low toxicity (Toxicity Category III), and no significant dermal irritation (Toxicity Category IV). Based on these results, the anticipated risks from dermal exposure are also considered minimal. Therefore, the risks from aggregate exposure via dermal and inhalation exposure are a compilation of two low risk exposure scenarios and are considered negligible.

#### 8. Cumulative Effects

MCP is not toxic and therefore there would be no expected cumulative effects from common mechanisms of toxicity.

#### 9. Risk Characterization

The Agency has considered MCP in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U. S. population in general, and to infants and children in particular, will result from the use of MCP when label instructions are followed.

#### B. ENVIRONMENTAL ASSESSMENT

# 1. Ecological Effects Hazard Assessment

The end use product EthylBloc® is intended for use in nonfood enclosed areas. When applied according to the proposed label, no direct exposure of birds, aquatic organisms and non-target insects to MCP is expected to occur. Thus, MCP's potential environmental/ecological effects are likely to be negligible. As a result, non-target organism/ecological effects studies were not required for this particular use of MCP.

#### 2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data (Tier II, (40 CFR Section 158.690(d)(2)(vii through xv)) was not triggered because of practically non-toxic results indicated in Tier I studies. Risk to nontarget species is minimal due to the lack of exposure, low toxicity, use pattern, and application methods.

# 3. Ecological Exposure and Risk Characterization

No potential for exposure exists to nontarget wildlife as a result of MCP's use.

#### C. EFFICACY DATA

No efficacy data are required, since no public health uses are involved.

# IV. SUMMARY OF DATA GAPS:

There are no data gaps for the use of MCP.

# V. CONTACT PERSON AT EPA

Driss Benmhend

Regulatory Action Leader

Biopesticides and Pollution Prevention Division (7511C) Office of Pesticide Programs Environmental Protection Agency 401 M Street, S.W. Washington, DC 20460

# Office location / telephone / e-mail

9th Floor (W9), Crystal Mall II 1921 Jefferson Davis Hwy. Arlington, VA 22202

(703) 308-9525 Benmhend.driss@epamail.epa.gov

**DISCLAIMER:** The information in this Pesticide Fact Sheet is a summary only and is not to be used to satisfy data requirements for pesticide registration and reregistration. Contact the Regulatory Action Leader listed above for further information.

# REGISTRATION ELIGIBILITY DOCUMENT

Methylcyclopropene (PC Code 224459)

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
Methylcyclopropene
(PC Code 224459)

#### **Table of Contents**

#### I. Executive Summary

- A. IDENTITY
- B. USE/USAGE
- C. RISK ASSESSMENT
- D. DATA GAPS / LABELING RESTRICTIONS

#### II. Overview

- A. ACTIVE INGREDIENT OVERVIEW
- B. USE PROFILE
- C. ESTIMATED USAGE
- D. DATA REQUIREMENTS
- E. REGULATORY HISTORY
- F. CLASSIFICATION
- G. FOOD CLEARANCES/TOLERANCES

#### III. Science Assessment

#### A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

- 1. Product Identity and Mode of Action
- 2. Food Clearances/Tolerances
- 3. Physical and Chemical Properties Assessment

#### B. HUMAN HEALTH ASSESSMENT

- 1. Toxicology Assessment
  - a. Acute Toxicology
  - b. Mutagenicity and Developmental Toxicity
  - c. Subchronic Toxicity
  - d. Chronic Exposure and Oncogenicity Assessment
  - e. Effects on Immune and Endocrine Systems
- 2. Dose Response Assessment
- 3. Dietary Exposure and Risk Characterization
- 4. Occupational, Residential, School and Day care Exposure and Risk Characterization
  - a. Occupational Exposure and Risk Characterization
  - b. Residential, School and Day Care Exposure and Risk Characterization
- 5. Drinking Water Exposure and Risk Characterization
- Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children
- Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation
- 8. Cumulative Effects
- 9. Risk Characterization

#### C. ENVIRONMENTAL ASSESSMENT

- 1. Ecological Effects Hazard Assessment
- 2. Environmental Fate and Ground Water Data
- 3. Ecological Exposure and Risk Characterization

#### D. EFFICACY DATA

#### IV. Risk Management Decision

# A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

#### B. REGULATORY POSITION

- 1. Conditional/Unconditional Registration
- 2. CODEX Harmonization
- 3. Nonfood Re/Registrations
- 4. Risk Mitigation
- 5. Endangered Species Statement

#### C. LABELING RATIONALE

- 1. Human Health Hazard
  - a. Worker Protection Standard
  - b. Non-Worker Protection Standard
  - c. Precautionary Labeling
  - d. Spray Drift Advisory
- 2. Environmental Hazards Labeling
  End-Use Product Environmental Hazards Labeling
- 3. Application Rate

#### D. LABELING

#### V. Actions Required by Registrants

#### VI. Appendix A

# I. Executive Summary

#### A. IDENTITY

Under normal environmental conditions, the active ingredient methylcyclopropene is a gas. The end-use product EthylBloc® is a white powder. It contains 0.43% of 1- methylcyclopropene (hereafter referred to as methylcyclopropene and abbreviated as MCP). When EthylBloc® is mixed with water or a buffer solution, it releases the gas MCP. The end-use product is manufactured by an integrated process. The product chemistry data submitted by the registrant satisfies the requirement for product identity.

#### B. USE/USAGE

MCP is to be used in confined areas to extend the life and usefulness of fresh cut flowers and potted flowering, bedding, nursery and foliage plants by inhibiting the negative effects of ethylene. Plants are treated in enclosed areas such as rooms, coolers, greenhouses, truck trailers and shipping boxes/containers. The use is classified as indoor non-food crops application.

#### C. RISK ASSESSMENT

No unreasonable adverse effects are anticipated from aggregate exposure to MCP. This includes all anticipated exposures for which there is reliable information.

#### 1. Human Health Risk Assessment

# a. Toxicological Endpoints

No toxicological endpoints were identified. Mammalian toxicology data requirements have been submitted and adequately satisfy data requirements to support the registration. Submitted data indicate Toxicity Category IV for acute oral and acute inhalation toxicity. Acute dermal toxicity data indicated a Toxicity Category III. The data reported for primary eye irritation and dermal irritation studies showed that the test substance was minimally irritating, and was given a Toxicity Category III for eye irritation and Toxicity IV for dermal irritation. Moreover, the mammalian mutagenicity studies submitted, demonstrated that MCP was not a mutagenic agent.

#### b. Human Exposure

Human exposure would be very low because of the absence of human activity in the enclosed and fairly gas tight areas where MCP is used. Moreover, the label's mitigating language and the quick dissipation of MCP following its application reduce further the chances of human exposure.

#### c. Risk Assessment

BPPD has not identified any subchronic, chronic, immune, endocrine, or nondietary exposure issues as they may affect children and the general U.S. population. Risk to applicators is mitigated as long as the product being registered at this time is used according to label directions. No toxicological endpoints have been identified, and there is limited exposure to this product when used according to label instructions. The Agency has considered MCP in light of the relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and has determined that there will be no unreasonable adverse effects from the use of this product.

# 2. Ecological Risk Assessment

# a. Ecological Toxicity Endpoints

No toxic endpoints were identified.

# b. Ecological Exposure

Information regarding nontarget organisms was waived based of the minimal exposure to MCP. The enclosed areas treated which originally have a minimal nontarget organisms activity (i.e. greenhouses), are fairly gas tight to reduce leakage. As a result, exposure outside the treated areas can also be considered minimal.

#### c. Risk Assessment

Risk to nontarget organisms is expected to be minimal, due to the low chances of exposure to MCP. As a result, BPPD believes that the use of MCP according to label use directions, should result in no significant adverse effects to wildlife.

# D. DATA GAPS / LABELING RESTRICTIONS

There are no data gaps.

# I. Overview

#### A. ACTIVE INGREDIENT OVERVIEW

Common Name:

EthylBloc®

Chemical Name:

1-Methylcyclopropene

Chemical Formula:

C<sub>10</sub>H<sub>18</sub>O

Chemical Family:

Methylcyclopropene

Trade and Other Names:

**MCP** 

**CAS Registry Number:** 

3100-04-7

**OPP Chemical Code:** 

224459

Basic Manufacturer:

Made onsite

Biotechnologies for Horticulture, Inc.

751 Thunderbolt Road Walterboro, SC 29488

#### B. USE PROFILE

The following, is information on the proposed uses with an overview of use sites and application methods.

Type of Pesticide: Plant Growth Regulator

Use Sites: Enclosed indoor use on fresh cut flowers and potted flowering, bedding, nursery and foliage plants. Plants are treated in enclosed areas such as rooms, coolers, greenhouses, truck trailers and shipping boxes/containers.

Target: Inhibit the effect of Ethylene

Formulation Types: Powder

Method and Rates of Application: To release the active ingredient (MCP), the end-use product EthylBolc® is mixed with water or buffer solution. The mixing container should be made of plastic. The amount of buffer solution and duration of the treatment (exposure time to MCP) vary with the temperature of the area treated:

a- At a temperature of at least 55°F, 1 scoop (1.5 grams) of EthylBolc® is to be mixed with 1 ounce of the buffer solution in order to treat a space of 100 cubic feet. The treatment time should be between 4 to 8 hours. At this dosage, a rate of 900 part per billion (ppb) of MCP will be released. If a longer treatment time (12 to 16 hours) is needed, the same dosage of EthylBolc® (1.5 grams in 1 ounce of the buffer solution) can be used to treat an enclosed area of 200 cubic feet. In this case, MCP release will be at a level of 450 ppb.

b- At temperatures between 35° and 55°F, 1 scoop of EthylBloc® is to be mixed in 1.5 ounce of the buffer solution, and used to treat an enclosed space of 100 cubic feet. The amount of MCP released will be at 900 ppb. A minimum treatment time of 10 hours is required under these conditions.

Use Practice Limitations: For use only on ornamental non-food crops in enclosed areas.

Timing: Application should be made just prior to harvest, immediately after harvest, prior to shipment, upon arrival from the supplier, and/or just prior to sale. Repeat at weekly intervals.

### C. ESTIMATED USAGE

None used yet since this will be the first registered product.

# D. DATA REQUIREMENTS

The mammalian toxicology and ecological effects data requirements for MCP have been fulfilled. Product analysis data requirements are adequately satisfied. The data requirements for granting this registration under Section 3(c)(5) of FIFRA have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD). Based on submitted information, the Agency foresees no unreasonable adverse effects to human health and the environment from the use of this chemical and recommends an unconditional registration of this new active ingredient for the proposed uses.

### E. REGULATORY HISTORY

On September 27, 1997, the Agency received an application from Biotechnologies for Horticulture, Inc. to register EthylBolc® containing 0.43% of 1-methylcyclopropene as a plant growth regulator.

A notice of receipt of the application for registration of 1-methylcyclopropene as a new active ingredient was published in the Federal Register on March 10, 1999 (64 FR 11868) with a 30-day comment period. No comments were received as a result of this publication.

#### F. CLASSIFICATION

The Biochemical Classification Committee determined that the MCP gas has not been shown to occur naturally, and can not be proved to fit the biochemical pesticide definition. However, the low use rates of MCP and its non-persistence and non-toxic mode of action, make this plant growth regulator eligible for a reduced data set similar to that used for biochemical pesticides applied to non-food crops in greenhouses.

# G. FOOD CLEARANCES/TOLERANCES

A numeric tolerance or exemption from the requirement of a tolerance is not needed because there are no food uses associated with the registration of MCP.

#### III. Science Assessment

#### A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for MCP are satisfied.

# 1. Product Identity and Mode of Action

#### a. Product Identity:

There is no TGAI for MCP. The end-use product has to be mixed with water or a buffer solution in order to release the active ingredient (gas) MCP which has the chemical formula  $C_{10}H_{18}O$ . The end-use product EthylBloc® which is a white powder, contains 0.43% of MCP, and is manufactured by an integrated process. The product chemistry data submitted by the registrant satisfies the requirement for product identity.

#### b. Mode of Action:

MCP which is considered a plant growth regulator, has a non-toxic mode of action. It acts as an inhibitor of ethylene by blocking the attachment of ethylene to plant and flower tissue, and thus prolongs the life of cut flowers and plants.

#### 2. Food Clearances/Tolerances

There are no food uses associated with this action. As a result, a tolerance establishment/exemption is not an issue in this case.

### 3. Physical And Chemical Properties Assessment

Since there is no TGAI involved, the physical and chemical characteristics of the end-use product were submitted to support the registration. There are summarized in Table 1.

Table 1. Product chemistry data requirements

GUIDELINE NO.	STUDY	RESULTS	MRID NO.	
151B-10 151B-11 151B-12	Product identity; Manufacturing process; Discussion of formulation of unintentional ingredients	Submitted data satisfies the data requirements for product identity, manufacturing process, and discussion of formation of impurities	445170-01 444647-01 445170-02	
151B-13	Analysis of samples	Submitted data satisfy the data requirements for analysis of samples	444647-02	
151B-15	Certification of limits	ation of limits Limits listed in the CSF are adequate		
151B-16	Analytical method	GC/FID	44647-03	
151B-17	PHYSICAL / CHEMICAL PROPERTIES FOR THE EP			
151B-17(a)	Color	445676-01		
151B-17(b)	Physical State Powder		445676-01	
151B-17 <b>©</b>	Odor Faint, sweet		445676-01	
151B-17(d)	Melting point >300 °C; color changes from white to brown at 260 °C.		445676-01	
151B-17(e)	Boiling point Not Applicable			
151B-17(f)	Density/Specific 0.634 g/ml at 25 °C gravity		445676-01	
151B-17(g)	Solubility	152 g/L water	445676-01	
151B-17(h)	Vapor Pressure	NA		

GUIDELINE STUDY NO.		RESULTS	MRID NO.	
151B-17(I)	pH	3.92 (in a 5.02% aqueous solution	445676-01	
151B-17(j)	Stability	Stable between 0 and 37 °C, under artificial sunlight, and in aqueous solution	445676-01	
151B-17(k)	Flammability	Not Specified		
151B-17(I)	Storage stability	Not Specified		
151B-17(m)	Viscosity	NA		
151B-17(n)	Miscibility	NA	64	
151B-17(o)	Corrosion characteristics	Not Corrosive	445676-01	
151B-17(p) Octanol/water partition coef.		NA		

#### B. HUMAN HEALTH ASSESSMENT

The information submitted in support of the application for registration of EthylBloc® containing 0.43% of MCP adequately satisfies the requirements set forth in 40 CFR 158.690 (c) for biochemical pesticides for non-food indoor uses.

The overall toxicological risk from human exposure to MCP is considered negligible.

# 1. Toxicology Assessment

Adequate mammalian toxicology data are available and support registration of the active ingredient 1-methylcyclopropene.

# a. Acute Toxicity

The registrant submitted acceptable acute toxicity studies. Based on a lack of mortality observed in albino rats orally dosed with 5000 mg/kg of powdered product EthylBloc®, the oral LD<sub>50</sub> was >5000 mg/kg; tox category IV. Based on a lack of mortality observed in albino rabbits dermally dosed with

2000 mg/kg of powdered product, the LD<sub>50</sub> was >2000 mg/kg; tox category III. Based on a lack of mortality observed in albino rats exposed to 165 ppm of MCP gas for 4 hours, the LC<sub>50</sub> was >165 ppm; tox category IV. Ocular instillation of 0.1 ml of powdered product caused mild to moderate eye irritation symptoms (redness, chemosis) which cleared by 72 hours posttreatment; tox category III. Dermal application of 0.5 g of powdered product did not cause any dermal irritation symptoms up to 72 hours postdosing; tox category IV. Based on the data, the test substance is not considered to be a contact sensitizer. No hypersensitivity incidents have been reported. Additionally, 4100 person hours of MCP exposure have been experienced by humans without any known MCP-induced health related problems being reported.

# b. Mutagenicity and Developmental Toxicity

The registrant submitted acceptable mammalian and non-mammalian mutagenicity studies for MCP. Based on the data obtained from the Salmonella typhimurium microsome reverse mutation assay, MCP did not induce positive increases in the number of revertants. The data obtained from the mouse lymphoma forward mutation assay showed that MCP did not induce a significant increase in mutant cells relative to controls; no dose-response effects nor cell toxicity effects were observed. Based on the data obtained from the in vivo mouse microsomal assay, MCP did not induce increases in micronucleated PCEs (polychromatic erythrocytes) relative to vehicle controls; no bone marrow toxicity [measured as a decrease in PCE:NCE (normochromatic erythrocytes) ratio] was observed for any dose of test substance. Based on a lack of statistically significant data obtained from a reverse-mutation assay study a mouse lymphoma forward mutation study assay, and a mouse micronucleus study, MCP is not considered a mutagen.

Mammalian toxicity data for EthylBloc® submitted are summarized in Table 2.

Table 2. Toxicity data requirements

GUIDELINE NO.	STUDY	RESULTS	MRID NO.
TIER I			134
152-10	Acute oral toxicity in rats	Toxicity Category IV	444647-04
152-11	Acute dermal toxicity in rabbits	Toxicity Category III	444647-05
152-12	Acute inhalation toxicity in rats	Toxicity Category IV	444647-06

GUIDELINE NO.	STUDY	RESULTS	MRID NO.
152-13	Primary eye irritation in rabbits	Toxicity Category III	444647-07
152-14	Primary dermal irritation in rabbits	Toxicity Category IV	444647-08
152-15	Dermal sensitization in guinea pigs	Not a sensitizer	445170-05
152-16	Hypersensitivity incidents	No hypersensitivity incidents observed	445170-06
152-17	Genotoxicity - Salmonella typhimurium gene mutation assay	Not mutagenic	444647-09
152-18	Cellular immune response	Waived	1 2 - 1
152-19	Mutagenicity:  * Mouse Lymphoma forward mutation  * In vivo mouse micronucleus assay	Not mutagenic	444647-10 444647-11

# c. Subchronic Toxicity

A 90 - day feeding study was not required because of the non-food use of MCP. Moreover, the 90 - day dermal and inhalation toxicity studies are not required because the proposed use pattern does not result in prolonged exposure at concentrations that are likely to be toxic. The immunotoxicity study (cellular immune response study) was waived based on the minimal potential for exposure and the low toxicity of MCP shown in the studies submitted.

# d. Chronic Exposure and Oncogenicity Assessment

Chronic exposure studies are conditionally required to support non-food uses only if the potential for adverse chronic effects are indicated based on 1) the subchronic effect levels established in Tier I subchronic oral, inhalation, or dermal studies, 2) the pesticide use pattern, or 3) the frequency and the level of repeated human exposure that is expected. Oncogenicity studies are required to support non-

food uses only if the active ingredient or any of its metabolites, degradation products, or impurities produce in Tier I studies morphologic effects in any organ that potentially could lead to neoplastic changes. The triggers for chronic exposure and oncogenicity studies were not met.

# e. Effects on the Endocrine Systems

The agency is not requiring information on the endocrine effects of this compound at this time. Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects. However, BPPD has considered, among other relevant factors, available information concerning whether MCP has an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known evidence so far that the active ingredient act as an endocrine disruption in humans. No adverse effects to the endocrine system are known or expected.

# 2. Dose Response Assessment

No toxicological endpoints are identified.

# 3. Dietary Exposure and Risk Characterization

Dietary exposure is unlikely to occur because of the non-food use of MCP. In the absence of any toxicological endpoints, risk from the consumption of residues is not expected for the general population including infants and children.

# 4. Occupational, Residential, School and Day Care Exposure and Risk Characterization

Human exposure to MCP is not expected in these areas.

# a. Occupational Exposure

Based on its low toxicity and its use on ornamentals intended for aesthetic purposes, MCP is not subject to the Worker Protection Standards (WPS). Moreover, the possibility for dermal, eye and inhalation exposure, is mitigated as long as the product is used according to label directions which recommends the use of protective equipment by users, posting signs to keep people out of treated areas, and allowing proper ventilation time before permitting human activity in the treated areas.

# b. Residential, School and Day Care Exposure and Risk Characterization

No indoor residential, school, or day care uses currently appear on proposed labels.

# 5. Drinking Water Exposure

Exposure to MCP in drinking water is not expected.

# 6. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

There are no food uses associated with the proposed use of the MCP. Therefore, the acute dietary risks should be negligible based on the lack of exposure.

# 7. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

Aggregate exposure would primarily occur in the applicators subpopulations via dermal and inhalation routes. Risks associated with dermal and inhalation aggregate exposure are measured via the acute toxicity studies submitted to support registration. Because the inhalation toxicity studies for MCP showed no toxicity (Toxicity Category IV), the risks anticipated for this route of exposure are considered minimal. Results of the acute dermal study indicated low toxicity (Toxicity Category III), and no significant dermal irritation (Toxicity Category IV). Based on these results, the anticipated risks from dermal exposure are also considered minimal. Therefore, the risks from aggregate exposure via dermal and inhalation exposure are a compilation of two low risk exposure scenarios and are considered negligible.

#### 8. Cumulative Effects

MCP is not toxic and therefore there would be no expected cumulative effects from common mechanisms of toxicity.

#### 9. Risk Characterization

The Agency has considered MCP in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U. S. population in general, and to infants and children in particular, will result from the use of MCP when label instructions are followed.

#### C. ENVIRONMENTAL ASSESSMENT

# 1. Ecological Effects Hazard Assessment

The end use product EthylBloc® is intended for use in non-food enclosed areas. When applied according to the proposed label, no direct exposure of birds, aquatic organisms and non-target insects

to MCP is expected to occur. Thus, MCP's potential environmental/ecological effects are likely to be negligible. As a result, non-target organism/ecological effects studies were not required for this particular use of MCP.

### 2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data (Tier II, (40 CFR Section 158.690(d)(2)(vii through xv)) was not triggered because of practically non-toxic results indicated in Tier I studies. Risk to nontarget species is minimal due to the lack of exposure, low toxicity, use pattern, and application methods.

# 3. Ecological Exposure and Risk Characterization

No potential for exposure exists to nontarget wildlife as a result of MCP's use.

#### D. EFFICACY DATA

No efficacy data are required, since no public health uses are involved.

# IV. Risk Management Decision

#### A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (c) it will perform its intended function without unreasonable adverse effects on the environment and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

To satisfy criteria "A" above, MCP is not expected to cause unreasonable adverse effects when used according to label instructions. Criteria "B" is satisfied by the current label and by the data presented in this document. It is believed that this new pesticidal active ingredient will not cause any unreasonable adverse effects, will extend the life and usefulness of ornamentals as claimed satisfying Criteria "C". Criteria "D" is satisfied in that the toxicological properties of this product are less toxic than any other conventional pesticide product currently in use.

Therefore, MCP is eligible for registration. Registered use is listed in Table 4, Appendix A.

#### B. REGULATORY POSITION

### 1. Conditional/Unconditional Registration

All data requirements are fulfilled and BPPD recommends unconditional registration of MCP.

#### 2. CODEX Harmonization

There are no Codex harmonization consideration since there is no food use associated with this registration.

# 3. Nonfood Re/Registrations

There are no non-food issues at this time. The nonfood uses are listed in Appendix A, Table 4.

### 4. Risk Mitigation

Since there are no risk issues, risk mitigation measures are not required at this time.

# 5. Endangered Species Statement

Currently, the Agency is developing a program (The Endangered Species Protection Program) to identify all pesticides whose use may cause potential adverse impacts on endangered and threatened species and their habitats. To aid in the identification of threatened and endangered species and their habitats, several companies have formed an Endangered Species Task Force (EST) under the direction of the American Crop Protection Association (ACPA). Moreover, the EST will assist in providing species location information at the subcounty level, and particularly if an endangered species occurs in areas where pesticides would be used. This information will be useful once the Endangered Species Protection Program has been implemented.

Prior to the implementation of the Endangered Species Protection Program, the Agency will not impose specific labeling on those pesticides that may pose risks to threatened and endangered species and their habitats but will defer imposing specific labeling language until implementation of the Program.

### C. LABELING RATIONALE

It is the Agency's position that the labeling for EthylBloc® containing 0.43% of 1-methylcyclopropene complies with the current pesticide labeling requirements.

- 1. Human Health Hazard
- a. Worker Protection Standard

This product does not come under the provisions of the Worker Protection Standards (WPS).

#### b. Non-Worker Protection Standard

There are no non-WPS human health hazard issues.

### c. Precautionary Labeling

The Agency has examined the toxicological data base for MCP product and concluded that the proposed precautionary labeling (i.e. Signal Word, Statement of Practical Treatment and other label statements) adequately mitigates the risks associated with the proposed uses.

End-Use product Precautionary Labeling: For EthylBloc®, "CAUTION". Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Harmful if inhaled. Avoid breathing vapor. Remove contaminated clothing and wash clothing before reuse.

# d. Spray Drift Advisory

No spray drift advisory statement is necessary for this use

# 2. Environmental Hazards Labeling

End-Use Product Environmental Hazards Labeling: Because MCP is exclusively intended for indoor use, the environmental hazard statement is not required on the end-use product's label.

# 3. Application Rate

It is the Agency's position that the labeling for the pesticide product containing MCP complies with the current pesticide labeling requirements. The Agency has not stipulated a maximum number of applications for the active ingredient. However, a specified maximum amount of the active ingredient per application is being required as follows:

At a temperature of at least 55°F, 1 scoop (1.5 grams) of EthylBolc® is to be mixed with 1 ounce of the buffer solution in order to treat a space of 100 cubic feet. The treatment time should be between 4 to 8 hours. At this dosage, a rate of 900 part per billion (ppb) of MCP will be released. If a longer treatment time (12 to 16 hours) is needed, the same dosage of EthylBolc® (1.5 grams in 1 ounce of the buffer solution) can be used to treat an enclosed area of 200 cubic feet. In this case, MCP release will be a level of 450 ppb.

At temperatures between 35° and 55°F, 1 scoop of EthylBloc® is to be mixed in 1.5 ounce of the buffer solution, and used to treat an enclosed space of 100 cubic feet. The amount of MCP released will be at 900 ppb. A minimum treatment time of 10 hours is required under these conditions.

### D. LABELING

# (1) Product name: EthylBloc®

1-methylcyclopropene	0.43%
Other Ingredients	

Signal word is "CAUTION". Eye irritation warning is appropriate.

The product shall contain the following information:

- Product Name
- Ingredient Statement
- Registration Number
- "Keep Out of Reach of Children"
- Signal Word (CAUTION)

# V. Actions Required by Registrants

Reports of incidences of adverse effects to humans or domestic animals under FIFRA, Section 6(a)2 and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16. There are no data requirements, label changes and other responses necessary for the reregistration of the end-use product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. There are also no existing stocks provisions at this time.

# vi. Appendix A

Table 4 lists the use sites for the product. The label for the product is also attached.

Table 4. Indoor Non-food Use Site Registration/Reregistration

EthylBloc®	Official date registered:
Use Sites Fresh cut flowers and potted flowering, bedding, nursery and foliage plants.	



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAR -1 1999

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

#### **MEMORANDUM**

SUBJECT: Registration of EthylBloc™ (EPA Symbol. No. 071297-R) containing 0.43% 1-

Methylcyclopropene (Chemical No. 224459), a new active ingredient. Review of Product Chemistry Data (Submission No. S555763; Case No. 063215), MRID

No. 44735401; DP Barcode D253250.

FROM: Russell S. Jones, Ph.D., Biologist

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division (7511C)

THRU: Freshteh Toghrol, Ph.D., Senior Scientist

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division (7511C)

TO: Driss Benmhend, Regulatory Action Leader

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division (7511C)

# **ACTION REQUESTED**

In response to a BPB request for additional information (Memorandum from R. S. Jones to D. Benmhend, dated 12/23/98), BioTechnologies for Horticulture, Inc. has submitted additional product chemistry data in support of the registration of EthylBloc<sup>TM</sup> (EPA Symbol. No. 071297-R) containing 0.43% 1-Methylcyclopropene (MCP) as its active ingredient; MCP is a new active ingredient. EthylBloc<sup>TM</sup> is a powdered product that changes to a gas phase (MCP) when mixed with water or a buffering agent. It is intended for non-food use floral and nursery crops.

The submitted product chemistry data includes a clarification of the manufacturing process and the suppliers of the product ingredients, revised certified limits for the basic formulation, revised Confidential Statements of Formula (CSFs) for the basic and alternate formulations (each dated 1/1/99), and a revised label.

#### CONCLUSIONS AND RECOMMENDATIONS

- 1. The supplemental information submitted to clarify the alternate formulations manufacturing process (151-11) is acceptable for registration. No additional data are required.
- 2. The revised CSF for the basic formulation is acceptable; no additional data are required.
- The revised CSF for the alternate formulation is acceptable; no additional data are required.
- 4. The revised first aid and precautionary statements on the product label are satisfactory.

#### STUDY SUMMARIES

# **Product Chemistry**

Supplemental product chemistry data were submitted for the manufacturing process (151-11) and certified limits (151-15). Statements regarding "equivalent" (but unspecified) beginning materials have been removed from the description of the manufacturing process. The manufacturing process for the alternate formulation was clarified and was found to be acceptable. Satisfactory certified limits (including an explanation of how the certified limits were determined for the inerts) for both the basic and alternate formulations were also reported, and revised CSFs for the basic and alternate formulations were submitted.

Classification: Acceptable. No additional data are required.

cc: R. Sjoblad, R. S. Jones, D. Benmhend, BPPD Subject File

R. S. Jones: F.T. CM2, (703) 308-5071: 2/24/99

# CONFIDENTIAL APPENDIX

The Following Section Contains Confidential Business Information (CBI)

# DATA EVALUATION REPORT

Primary Reviewer: Secondary Reviewer: Russell S. Jones, Ph.D., BPPD Freshteh Toghrol, Ph.D., BPPD

STUDY TYPE:

Product Chemistry (Subdivision M Guidelines 151-10 to 151-17)

TOX, CHEM. No.:

None

CASE No.

063215

PC CODE:

224459

DP BARCODE:

D249432

SUBMISSION No.:

S555763

MRID Nos:

44735401

TEST MATERIAL:

EthylBloc<sup>TM</sup>

STUDY Nos.:

None

SPONSOR:

BioTechnologies for Horticulture, Inc.,571 Thunderbolt Road,

Walterboro, SC 29488.

**TESTING FACILITIES:** 

None

TITLE OF REPORTS:

Manufacturing Process and Certified Limits for EthylBloc® -

Supplemental Data.

**AUTHORS:** 

Amy Plato Roberts, Technology Sciences Group, Inc., 1101 17th

Street, N.W., Suite 500, Washington, DC 20036.

REPORT ISSUED:

January 13, 1999

OUALITY ASSURANCE: The study was not conducted under Good Laboratory Practices (GLP) guidelines because the studies were discussions and or summaries that contained no scientific data. Statements of non-

compliance were signed by the study author.

CLASSIFICATION:

Acceptable. No additional data are required.

# I. MANUFACTURING PROCESS (151-11; MRID 44735401)

The manufacturing process was described in detail in a previous review (see Memorandum from R. S. Jones to D. Benmhend, dated 12/23/98). The registrant submitted a brief clarification of the alternate formulation manufacturing process and clarified why was used to formulate the end-use product. It was further explained how variations in the amount of used in the manufacture of the product could cause relatively large range in the certified limits for these two inert ingredients.

# II. CERTIFICATION OF INGREDIENTS (151-15) MRID 44517003

The revised nominal concentrations and certified ingredient limits (by % weight) for the basic formulation were as follows:

Ingredient	Nominal Concentration*	Certified Limits (% by weight)*	
	% by weight	Upper	Lower
1-Methylcyclopropene	0.430	0.47	0.39

<sup>\*</sup>CSF dated 1/13/99

The limits for the inert ingredient were changed from the original submission to show that the upper limit would not exceed 100% of the product by weight.

The nominal concentrations and certified ingredient limits (by % weight) for the alternate formulation were as follows:

Ingredient	Nominal Concentration*	Certified (% by v	
	% by weight	Upper	Lower
1-Methylcyclopropene	0.430	0.47	0.39

<sup>\*</sup>CSF dated 11/97

An explanation for the wide variation in the certified limits for the inerts is contained in the description of the manufacturing process (151-11) above.

# STUDY DEFICIENCIES

None

# **CLASSIFICATION:**

Acceptable; no additional data are required.

# U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

BIOTECHNOLOGIES FOR HORTICULTURE, INC. 751 THUNDERBOLT ROAD WALTERSBORO, SC 29488

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 01/19/99. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



WASHINGTON

1101 17th Street, N.W.

Roy Sjoblad - PM 91

January 13, 1999

Suite 500

Driss Benmhend

Washington D.C. 20036

Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

Te ephone 202 223-4392

Office of Pesticide Programs

Fax 202 872-0745

1921 Jefferson Davis Highway, CM2

Arlington, VA 22202

RE: Application for registration of EthylBloc®, EPA File Symbol 71297-R Response to Agency letter dated January 6, 1999

SAN FRANCISCO

Dear Messrs. Sjoblad and Benmhend:

2700 Steuart Street Tower

One Market

San Francisco, CA 94105

Telephone 415 267-4119

Fax 415 267-4198

In response to the Agency's letter dated January 6, 1999, and the Agency's review dated December 23, 1998, on the registration of EthylBloc®, enclosed you will find the following:

- 1) Revised Confidential Statements of Formula for the basic formulation and an alternate formulation;
- 2) One (1) copy of a revised product label with all changes highlighted;
- 3) Two (2) copies of a clean, revised product label;
- 4) Volume 1 of 2 Transmittal Document;
- 5) Volume 2 of 2 Manufacturing Process and Certified Limits for EthylBloc® Supplemental Data.

As you will note in the enclosed documents, we have addressed those data that were determined "unacceptable but upgradeable" by the review. Should you have any questions or comments, please do not hesitate to let me know.

SACRAMENTO

712 Fifth Street

Suite A

Davis , CA 95616

elephone 530 757-1298

Fax \$30 757-1299

Sincerely,

Amy Plato Roberts

Regulatory Consultant for BioTechnologies for Horticulture

Direct dial (202) 828-8964

E-mail tsg@tsgusa.com

http://www.tsgusa.com

#### VOLUME 1 OF 2 OF SUBMISSION

### TRANSMITTAL DOCUMENT

#### NAME AND ADDRESS OF SUBMITTER:

BioTechnologies for Horticulture, Inc. 751 Thunderbolt Road Waltersboro, SC 29488

#### **REGULATORY ACTION:**

Submission of supplemental data in support of EthylBloc® (EPA File Symbol 71297-R)

### TRANSMITTAL DATE:

January 13, 1999

#### LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDELINE NUMBER
	1 of 2	(Transmittal Document)	
4473540	2 of 2	Manufacturing Process and Certified Limits For EthylBloc® - Supplemental Data	OPPTS 885.1200 OPPTS 885.1500

**COMPANY NAME:** 

BioTechnologies for Horticulture, Inc.

**COMPANY OFFICIAL:** 

Amy Plato Roberts, Regulatory Agent

**COMPANY CONTACT:** 

Amy Plato Roberts, Regulatory Agent Technology Sciences Group, Inc.

1101 17th Street, N.W. Washington, DC 20036

(202) 828-8964

Page 1 of 1



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JAN - 6 1999

Amy Plato Roberts
Technology Sciences Group, Inc.
1101 17th Street, N.W., Suite 500
Washington, DC 20036

Subject:

Application for Registration of EthylBloc® (containing 0.43% of 1-

Methylcyclopropene)

EPA Registration No. 71297-R Your Submission of March 18, 1998

Dear Amy:

The data submitted in support of the submission listed above was reviewed. BPPD found several deficiencies in the manufacturing process, and the Confidential Statement of Formula (CSF). These deficiencies are upgradable and have to be addressed before a further consideration is given to your application.

We have attached a copy of the review summary. Please go over it, and make the recommended corrections.

This application will be kept open for a period of 75 days to give you an opportunity to correct the deficiencies listed in the attached review summary. If you find that you need more time to satisfy the requirements, you should request an extension and commit yourself to satisfy the deficiencies within a reasonable period of time. If you do not comply with these procedures, the Agency may administratively withdraw your application from further consideration, and retire this file without further notice to you in accordance with the policy established by the PR Notice 75-4 of August 27, 1975. Once this is done, you will have to submit a complete new •

Reid 1/11/99 APPL

application should you wish to pursue the registration of you your product after the application has been withdrawn.

Sincerely,

Roy Stoblad, Ph. D., Chief Biochemical Pesticides Branch

Biopesticides and Pollution Prevention Division (7511C)

Enclosures



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

DEC 23 1998

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

#### **MEMORANDUM**

SUBJECT: Registration of EthylBloc™ (EPA Symbol. No. 071297-R) containing 0.43% 1-

Methylcyclopropene (Chemical No. 224459), a new active ingredient. Review of

Product Chemistry and Toxicity Data (Submission No. S548591; Case No. 063215), MRID Nos. 444647-01, -02, -03, -04, -05, -06, -07, -08, -09, -10, and -11; 4451700-01, -02, -03, -04, -05, and -06; and 445676-01; DP Barcode

D249432.

FROM: Russell S. Jones, Ph.D., Biologist

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division (7511C)

THRU: Freshteh Toghrol, Ph.D., Senior Scientist

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division (7511C)

TO: Driss Benmhend, Regulatory Action Leader

Biochemical Pesticides Branch

Biopesticides & Pollution Prevention Division (7511C)

# **ACTION REQUESTED**

BioTechnologies for Horticulture, Inc. requests registration of an end-use product, EthylBloc™ (EPA Symbol. No. 071297-R) containing 0.43% 1-Methylcyclopropene (MCP) as its active ingredient; MCP is a new active ingredient. EthylBloc™ is a powdered product that releases a gas (MCP) when mixed with water or a buffering agent. It is intended for non-food use floral and nursery crops.

In support of the registration, the registrant has submitted product chemistry and toxicity studies, a proposed product label, and Confidential Statements of Formula (CSFs) for the basic formulation and one alternate formulation (each dated 11/97). Material Safety Data Sheets (MSDS) were submitted for each of the product ingredients. The registrant did not submit nontarget organism/ecotoxicity studies or request a waiver from the requirements for these studies.

CONCLUSIONS AND RECOMMENDATIONS

- 1. BPB does not support the registration of EthylBloc™ because of deficiencies in the description of the manufacturing process (151-11), and in the certified limits (151-15) and Confidential Statement of Formula (CSF) for the alternate formulation.
- 2. The data submitted for product identity and disclosure of ingredients (151-10), the discussion of the formation of unintentional ingredients (151-12), preliminary analysis (151-13), analytical methods (151-16), and physical/chemical properties (151-17) are acceptable. No additional data are required.
- 3. The description of the manufacturing process (151-11) is unacceptable, but upgradable. For each beginning material used in the manufacturing process, the registrant indicated that an "equivalent" material could be substituted, but none of these equivalent materials were identified. To upgrade the study, the registrant must submit a list of all the beginning materials (and substitutes), MSD sheets, and the names and addresses of all their respective suppliers. The registrant must also indicate when each substitute beginning material may be used in the manufacturing process and the amount of each substitute material that is used.
- 4. The certified limits (151-15) for an inert ingredient in the alternate formulation are unacceptable, but upgradable. To upgrade the data, the registrant must specify the correct upper and lower limits of the substitute inert ingredient; the currently listed limits are too large. The certified limits for this inert ingredient should be ± 3% of the nominal concentration (by % weight). These data must agree with the information listed on a revised alternate formulation CSF.
- 5. The registrant must submit a revised CSF for the alternate formulation. The alternate formulation CSF should list only the active ingredient and the substitute inert ingredient that is used in place of the inert listed for the basic formulation. The certified limits for the substitute inert ingredient must be  $\pm$  3% of the nominal concentration (see above).
- 6. No additional data are required for acute mammalian toxicity (152-10 to 152-16). The product is not a sensitizing agent.
- 7. No additional data are required for mutagenicity (152-19). Based on the data, the product is not a mutagen.
- 8. No data were submitted for non-target organisms/ecological effects (154-6 to 154-11), but none are required for EthylBloc<sup>TM</sup>. The product is non-food use and is not intended for use outdoors or in other non-enclosed areas. If the registrant intends to use this product (or other products containing MCP as the active ingredient) on food crops/commodities, outdoors and/or in other non-enclosed areas, or in enclosed areas

where non-target insects and plants may be exposed, additional non-target organism/ecological effects studies may be required.

9. A revised label must be submitted (see Label Review below).

#### STUDY SUMMARIES

# **Product Chemistry**

Product chemistry data (Subdivision M Guidelines 151-10 through 151-17 were presented for EthylBloc<sup>TM</sup> (MRIDs 444647-01, -02, and -03; 4451700-01, -02, -03, and -04; and 445676-01). The end-use product consists of one basic formulation. The new biochemical active ingredient is1-methylcyclopropene, which comprises 0.43% of the product by weight. The submitted preliminary analysis data were satisfactory. Acceptable certified ingredient limits (by % weight) were reported for the basic formulation, but not for the alternate formulation; the range for the upper and lower certified limits was large. New certified limits for one inert ingredient in the alternate formulation must be submitted and a second inert ingredient must be removed from the ingredients list. A revised alternate formulation CSF must be submitted to reflect these changes. An acceptable GC/FID method for the determination of the active ingredient in the end-use product was presented; precision, accuracy, and limits of detection data were reported, and representative chromatograms were submitted. The data submitted for physical/chemical properties were satisfactory.

Study deficiencies: (i) for each beginning material used in the manufacturing process (151-11), the registrant indicated that an "equivalent" material could be substituted, but none of these equivalent materials were identified; (ii) the range for the certified ingredient limits (151-15) for inert ingredients in the alternate formulation were incorrect; and (iii) an inert ingredient from the basic formulation was incorrectly listed on the alternate formulation CSF.

Classification: Unacceptable, but upgradable. To upgrade the study, the registrant must resolve the product chemistry deficiencies described above.

# Toxicology

The registrant submitted acceptable acute toxicity studies (152-10 to 152-16) and mutagenicity studies (152-19) for EthylBloc<sup>TM</sup>. Based on a lack of mortality observed in albino rats orally dosed with 5000 mg/kg of powdered product, the oral LD<sub>50</sub> was >5000 mg/kg; tox category IV. Based on a lack of mortality observed in albino rabbits dermally dosed with 2000 mg/kg of powdered product, the LD<sub>50</sub> was >2000 mg/kg; tox category III. Based on a lack of mortality observed in albino rats exposed to 165 ppm of MCP gas for 4 hours, the LC<sub>50</sub> was >165 ppm; tox category IV. Ocular instillation of 0.1 mL of powdered product caused mild to moderate eye irritation symptoms (redness, chemosis) which cleared by 72 hours posttreatment; tox category

III. Dermal application of 0.5 g of powdered product did not cause any dermal irritation symptoms up to 72 hours postdosing; tox category IV. Based on the data, the test substance is not considered to be a contact sensitizer. No hypersensitivity incidents have been reported. Approximately 4100 person hours of MCP exposure have been experienced by humans without any known MCP-induced health related problems being reported. Based on a lack of statistically significant data obtained from a reverse-mutation assay study a mouse lymphoma forward mutation study assay, and a mouse micronucleus study, MCP is not considered a mutagen.

Classification: Acceptable; no additional data are required.

### LABEL REVIEW

General: The signal word "CAUTION" that is listed on the proposed label is appropriate.

Toxicity: Acute toxicity studies demonstrate that the active ingredient should be classified in Toxicity Category III for acute dermal toxicity and primary eye irritation (Subdivision M Guidelines 152-11 and 152-13, respectively). Therefore, the product label must contain a Precautionary Statement and First Aid (Statement of Practical Treatment) statements appropriate for these toxicity categories. Appropriate label statements (obtained from the Label Review System) are attached.

cc: F. Toghrol, R. S. Jones, R. Kumar, BPPD Subject File R. S. Jones: F.T. CM2, (703) 308-5071: 12/23/98

# ATTACHMENT

Label Precautionary Statements and First Aid (Statement of Practical Treatment)
Statements

# CONFIDENTIAL APPENDIX

The Following Section Contains Confidential Business Information (CBI)

Date: 12/09/98

Page: 1

ID #: 071297-00001 ETHYLBLOC

SIGNAL WORD: CAUTION

#### PRECAUTIONARY STATEMENTS:

Harmful if absorbed through skin. Causes moderate eye irritation.

Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the teilet.

bethroom facilities

# STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF ON SKIN: Wash with plenty of soap and water. Get medical attention. For Category III, add "if symptoms persist."

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

United States

	Registration
	Amendment
/	Other

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

**OPP Identifier Number** 

<b>\$EPA</b>	Environmental Protection Washington, DC		Amendment  Other	259579
	Applica	ation for Pesticide - Se	ction I	
1. Company/Product Number 71297-R	or .	2. EPA Product M Driss Benmhen	d (702) 200 0525 F	Proposed Classification  None Restricted
4. Company/Product (Name EthylBloc	)	PM# BPPD		
751 Thunderbolt Walterboro, SC 2	for Horticulture, Inc Road	(b)(i), my produc to:	eveiw. In accordance wi	
		Section - II		
Notification - Explain	ponse to Agency letter dated	"Me Too" Other - E	xplain below.	ECEIVED OCI 9 1998 PP/BPPD
Revised labels, including appare highlighted.	olication rates in parts per billion (p	pb) and paragraph on posting (page	5), per EPA letter dated Sept	tember 21, 1998. All changes
1. Meterial This Product Wil		Section - III		
Child-Resistant Packaging Yes No * Certification must	Unit Packaging  Yes  No  If "Yes"  Unit Packaging wgt.  No. per Unit Packaging wgt.			C
3. Location of Net Contents		Retail Container	5. Location of Label Direc	
6. Manner in Which Label is		thograph Oth per glued enciled	vor	
		Section - IV		
1. Contact Point (Complete	items directly below for identific	estion of individual to be contacted	d, if necessary, to process th	nis application.)
Name Amy Plato Roberts		Title Regulatory Consultant		one No. (Include Area Code) 28-8964
	ments I have made on this form by knowlinglly false or misleading	fication and all attachments thereto are tr statement may be punishable by		6. Date Application Received (Stamped)
2. Signature	vS	3. Title Regulatory Consultant		
4. Typed Name Amy Plato Roberts		5. Date October 6,	1998	



October 13, 1998

#### WASHINGTON

1101 17th Street, N.W.

Suite 500

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Roy Sjoblad

Chief, Biochemicals Branch

Biopesticides and Pollution Prevention Division (7511C)

Office of Pesticide Programs, EPA 1921 Jefferson Davis Highway

Arlington, VA 22202

RE:

Letter of Authorization to discuss the product EthylBloc® (EPA File Symbol 70299-R) with the Pest Management Regulatory Agency of

Canada

Dear Roy:

2700 Steuart Street Tower

One Market

SAN FRANCISCO

San Francisco, CA 94105

Telephone 415 267-4119

Fax 415 267-4198

SACRAMENTO

712 Fifth Street

Suite A

Davis , CA 95616

Telephone 530 757-1298

Fax 530 757-1299

As discussed during our meeting on September 28, 1998 and during conversations with Driss Benmhend, the Regulatory Action Leader for this product, the Pest Management Regulatory Agency (PMRA) of Canada will be following EPA's registration of EthylBloc® so as to further its experience with registration processes that utilize reduced data sets for biochemical pesticides. As mutually agreed, EPA will be available to discuss the registration or share documents regarding EPA evaluation, as needed. Discussions are expected to be in the spirit of allowing PMRA to understand EPA's system of evaluating biochemical pesticides. Documents may include, but are not limited to, data reviews, EPA correspondence, application forms, labels and study details. The registrant will be responsible for providing PMRA with relevant documents; however, EPA is free to transmit documents if it so wishes.

With this letter we hereby authorize EPA to discuss matters regarding applications to register EthylBloc® with personnel at PMRA, including discussions regarding confidential business information, and to release written documents to PMRA, including those containing confidential business information.

We appreciate your assistance and participation in this collaboration with PMRA. Should you have any questions or comments please let me know.

7

Sincerely,

**Amy Plato Roberts** 

Regulatory Consultant for Biotechnologies for Horticulture

CC:

Driss Benmhend, BPPD, EPA

Janet Andersen, BPPD, EPA

Wayne Ormrod, PMRA
Jim Daly, Biotechnologies for Horticulture

E-mail tsg@tsgusa.com

http://www.tsgusa.com



Roy Sjobled
Chief, Biochemicals Branch
Blopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs, EPA
1921 Jefferson Davis Highway
Arlington, VA 22202

DE-

Technology Sciences Group Letter of Authorization, dated October 13, 1998, giving authorization to discuss the product EthylBioc® (EPA File Symbol 70299-R) with the Pest Management Regulatory Agency of Canada

Dear Mr. Sjoblad:

As discussed during our meeting on September 28, 1998 and as detailed in a letter of authorization from Technology Sciences Group (TSG) dated October 13, 1998, we are confirming authorization, as given by TSG, for EPA to discuss matters regarding applications to register EthylBloc® with personnel at PMRA, including discussions regarding confidential business information, and to release written documents to PMRA, including those containing confidential business information.

Sincegely

Jim Dety President

¢¢:

Oriss Benimhend, BPPD, EPA Janet Andersen, BPPD, EPA Wayne Ormrod, PMRA Amy Roberts, TSG

751 Thunderbolt Drive • Walterboro, SC 29488-9366

# NEW CHEMICAL/FIRST FOOD USE SCREEN

1.	FILE SYMBOL/REG NO (ISB)
2.	TOLERANCE PETITION NO. (RSB)
	CHEMICAL NAME (RSB) 1- Methy/Cyclopropere
4.	PESTICIDE CHEMICAL CODE. (RSB) 22449 (Cas: 3100-04-7)
5.	PRODUCT NAME (ISB)
	PM (ISB) 92 7. PM TEAM REVIEWER (PM)
8.	DATE OF RECEIPT (ISB) 12/11/97 (1/12/98 from 25B).
9.	USE PATTERN (PM)
10.	DATE OF TRANSMISSION TO PM (ISB) 1/13/98 De to \$516) (EPA Receipt Date plus 3 days)
11.	DATE OF TRANSMISSION TO HED/EFED/RSB (PM)  (PM Receipt Date plus 5 days)
12.	HED/EFED/RSB DUE DATE FOR COMPLETION OF SCREEN (HED/EFED Receipt Date plus 10 days)
13.	HED/EFED/RSB REVIEWERS: HED: EFED: EEEB
	DEB
	OREB
1	RD/RSB
14.	HED/EFED/RSB COMPLETION DATE (HED) (EFED) (RSB)
15.	SUBMISSION BARCODE (PM)
	REGISTRANT PHONE CONTACT INFORMATION (PM)
	DATE OF CONTACT STATUS OF PACKAGE
	PERSON CONTACTED Chamingty
	TITLE PASSED F.T. 4314
	DECISION & COMMENTS
-	FAILED SCREEN
-	(Documentation attached) 366
1	366

# NEW CHEMICAL/FIRST FOOD USE SCREEN

M110~ D	46
L. FILE SYMBOL/REG NO. (ISB)	
2. TOLERANCE PETITION NO. (RSB)	
3. CHEMICAL NAME (RSB) 1-Methylexclopropen	ie
4. PESTICIDE CHEMICAL CODE (RSB) 224459	(CAS: 3/00-04-7)
5. PRODUCT NAME (ISB)EThy/b/oc.	
6. PM (ISB) 92 7: PM TEAM REVIEWER (PM)	
3. DATE OF RECEIPT (ISB): 12/11/97 (1/12	198 FROM RSB)
USE PATTERN (PM)	(
0. DATE OF TRANSMISSION TO PM (ISB) 1/3/98 (EFA Receipt Date)	(Data to SIG) plus 3 days)
DATE OF TRANSMISSION TO HED/EFED/RSB (PM)	
(PM Rec	eipt Date plus 5 days)
2. HED/EFED/RSB DUE DATE FOR COMPLETION OF SCREEN (HED/EFED	Receipt Date plus 10 days)
3. HED/EFED/RSB REVIEWERS: HED: EFED: EEB	
DEB EFGWB	
OREB	
RD/RSB_	
A. HED/EFED/RSB COMPLETION DATE (HED)(BFEL	D)(RSB)
SUBMISSION BARCODE (PM)	
	1
REGISTRANT PHONE CONTACT INFORMATION (PM)	
DATE OF CONTACT	STATUS OF PACKAGE
PERSON CONTACTED_	
TITLE .	PASSED
DECISION & COMMENTS	SCREEN N// 3/03/gg
	FAILED (1/23/98 SCREEN (Documentation attached)
	attached)
	(Y) , 7 2/
	RV4123/98 367 (23/
	Kulz3/40 30/14/

# ATED REGISTRATION **Registration Priority Actions**

9/3/98 DATE:

ACTION(S):	REGISTRANT	ISSUES:	DECISIONS:
New Chemical Registration. A.I.: Methylcyclopropene MCP) Eligh Bloc Chem. Code: 224459 EPA Rer. 71297-R	BioTechnologies for Horticulture A PGR, used to extend life of cut flowers. Independent greenouse use.	inholation Study Registrant	Roye : Protecol for mutagenicity in the goe assay is inappropriate, since the goe
		has elgicisted waiver of	Need to do something about characteris
		How much gas per a gram of material? a	Exposure Elemanical should show and he reasonable certainty that there is the HIC exposure (£ 165 ppm in air).  on: The gas is encapsulated in the case
			sich is released when comes in

other (subcheomic) studies. s mentioned as an inest up no rex

concerns. Masces toxicology screen with the condition that exposure scenario info be submitted e minimum hisk, screen since data aggirements

#### U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

BIOTECHNOLOGIES FOR HORTICULTURE, INC. 122 TOWER DRIVE BURR RIDGE, IL 60521

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 05/28/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



May 27, 1998

Driss Benmhend
Biochemicals Branch
Biopesticides and Pollution Prevention Division (7511W)
2800 Crystal Drive, Crystal Station Bldg. 1
Arlington, VA 22207

EthylBloc®; EPA File Symbol 71297-R

EPA Letter dated April 30, 1998

1101 17th Street, N.W.

WASHINGTON

Suite 500

Washington, D.C. 20036

Telephone 202 223 4392

Fax 202 872 0745

: tsg@tsgusa.com

Dear Driss:

RE:

With this letter Technology Sciences Group, on behalf of Biotechnologies for Horticulture Inc., responds to the Agency's letter dated April 30, 1998 regarding the application for registration of EthylBloc®. Enclosed you will find the following information; each point corresponds with the points in your letter:

**CALIFORNIA** 

2700 Steuart Street Tower

One Market

San Francisco, CA 94105

Telepho e 415 267 4119

Fax 415 267 4198

1) Three (3) copies of pages 29 - 42 of the Beuhler Sensitization Test (Toxicon Laboratories) which were missing.

2) Three (3) copies of a corrected Statement of Data Confidentiality Claims for the Hypersensitivity Incidents Report.

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757 1298

Fax 530 757 1299

Three (3) copies of a study entitled "Physical and Chemical Properties of EthylBloc® - Part II." This study addresses the following physical and chemical data requirements detailed in your letter - listed as EPA Guideline (OPPTS Guideline): 63-2 (830.6302) Color; 63-3 (830.6303) Physical State; 63-4 (830.6304) Odor; 63-5 (830.7200) Melting Point; 63-14 (830.6314) Oxidizing or Reducing Action; 63-16 (830.6316) Explodability; 63-17 (830.6317) Storage Stability; and 63-20 (830.6320) Corrosion.

370



Page 2 May 27, 1998

WASHINGTON

1101 17th Street, N.W.

Suite 500

Washington, D.C. 20036

Telephone 202 223 4392

Fax 202 872 0745

tsg@tsgusa.com

**CALIFORNIA** 

2700 Steuart Street Tower

One Market

Sar Francisco, CA 94105

eprione 415 267 4119

Fax 415 267 4198

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757 1298

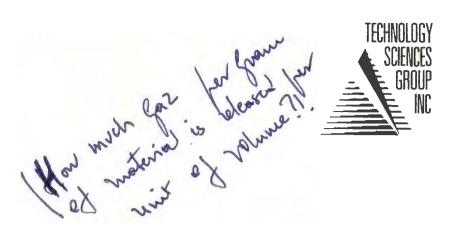
Fax 530 757 1299

4) For a greenhouse, non-food use site, non-target organism data is conditionally required for the following:

Data Requirement
Avian Oral
Avian Dietary
Freshwater Fish
Aquatic Invertebrate
Non-target Insect

For pesticides intended for indoor application only, these studies are required on a case-by-case basis depending upon use pattern, product volume and other pertinent factors. The Agency has requested a formal request for waivers of these studies. As such, with this letter we hereby request a waiver of the above listed data requirements, based on the following:

EthylBloc® is a powder which, when mixed with water or a buffer solution, releases a gas (1-Methylcyclopropene, MCP) that works to extend the life and usefulness of flowers and ornamental plants. The active ingredient inhibits the negative effects of ethylene which cause flower death, leaf or flower fall, and leaf yellowing. There are no reports of the active ingredient adversely effecting humans, animals or non-target organisms. The toxicity studies submitted to support registration indicate a toxicity category of IV for all routes of exposure with the exception of a toxicity category of III for eye irritation. EthylBloc® is intended for use as a gas in enclosed areas such as rooms, coolers, greenhouses, truck trailers, shipping boxes, and / or enclosures specifically constructed for EthylBloc® use. In all cases, the enclosed areas are fairly gas tight to reduce leakage and achieve maximum effectiveness. As such, exposure to the environment would be limited, especially in light of the gaseous nature of the material. The product is **not** intended for use outdoors and it is **not** intended for use on food crops. When applied as a gas according to the proposed method of use, no direct environmental exposure to birds, fish, aquatic organisms or non-target insects is expected to occur.



Page 3 May 27, 1998

WASHINGTON

1101 17th Street, N.W.

Suite 500

Washington, D.C. 20036

Telephone 202 223 4392

Fax 202 872 0745

tsg@tsgusa.com

CALIFORNIA

2700 Steuart Street Tower

One Market

San Francisco, CA 94105

Telepnone 415 267 4119

Fax 415 267 4198

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757 1298

Fax 530 757 1299

Subchronic inhalation and inhalation developmental toxicity studies are conditionally required if pesticidal use may result in repeated inhalation exposure at a concentration which is likely to be toxic, or in the case of teratogenicity, if there is expected to be a significant exposure to female humans and the use requires a tolerance or an exemption or an issuance of a food additive regulation. For the case of EthylBloc®, none of the above apply. As such, with this letter we hereby request a waiver of any further inhalation data requirements based on the following rationale:

The product was tested in an Acute Inhalation Toxicity study, the results of which were an LC<sub>50</sub> of greater than 165 ppm, which was the highest attainable concentration. There were no adverse effects or mortality in the test. As previously stated, toxicity studies have indicated that EthylBloc® is not toxic and is rated as toxicity category IV or III for all routes of exposure. The results of the acute inhalation study do not trigger further inhalation testing of the product. There is not expected to be repeated exposure at potentially toxic concentrations, there is not expected to be significant exposure to female humans and the use does not require a tolerance, an exemption or a food additive regulation. Lastly, the use of respiratory protective equipment is recommended on the product label (the protective equipment listed is greater than that which is required for a product rated toxicity category IV for inhalation route of exposure).

In close, we have updated the proposed product label to include modified directions for use and revised precautionary statements (per current guidelines). Enclosed you will find five (5) copies of the label, noted with a last revision date of May 27, 1998. Please replace exisiting label drafts with this updated version. Should you have any questions or comments, please let us know.

Sincerely

Amy Plato Roberts

Regulatory Consultant for Biotechnologies for Horticulture Inc.

(202) 828-8964

#### **VOLUME 1 OF 2 OF SUBMISSION**

#### TRANSMITTAL DOCUMENT

#### NAME AND ADDRESS OF SUBMITTER:

Biotechnologies for Horticulture, Inc. 122 Tower Drive Burr Ridge, IL 60521

#### **REGULATORY ACTION:**

Submission of additional product chemistry data for EthylBloc® (EPA File Symbol 71297-R)

#### TRANSMITTAL DATE:

May 27, 1998

#### LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	GUIDEL NE NUMBER
	1 of 2	(Transmittal Document)	
445676	2 of 2	Physical and Chemical Properties of EthylBloc® - Part II	OPPTS \$30.6302,830.6303. 830.6304. 830.7200, 833. 6314, 833.6316, 830.6317, 830.6321 (see title page for corresponding EPA Series 63 references)

**COMPANY NAME:** 

Biotechnologies for Horticulture, Inc.

**COMPANY OFFICIAL:** 

Amy Plato Roberts, Regulatory Agent

**COMPANY CONTACT:** 

Amy Plato Roberts, Regulatory Agent

Technology Sciences Group, Inc.

1101 17th Street, N.W. Washington, DC 20036

(202) 828-8964

Page 1 of 1

# Jess R. Martineau, Ph.D. Consultant Regulatory Affairs

10854 S. Green Ridge Drive Sandy, UT 84070 Phone (801) 572-4386 Fax (801) 523-0377

EMail Jesmartino @ AOL.COM\_

March 28, 1998

Dr. Roy Sjoblad
Biochemical Pesticides Branch
Biopesticides and Pollution Prev. Div. (7511W)
401 "M" Street, S.W.
Washington, DC 20460

RE: MCP, EthylBloc™

EPA Registration No. 71297-R

Dear Sir:

As of April 1, 1998, all correspondence regarding the subject registration application should be directed to:

Jim Daly BioTechnologies, for Horticulture 122 Tower Drive Burr Ridge, IL 60521

Phone (630) 325-1888

Jess R. Martinean

Jess R. Martineau, Ph.D. Regulatory Consultant

cc: Jim Daly, BioTechnologies for Horticulture Dr. George Staby, PRO

374

# BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen		MORE HIMPSON
	(ASSIGNED E	X: 5708100
EPA REG./FILE SYMBOL 7/297-R		
ACTION CODE		
ACTION CODE	A Stranger	ILEINSOCK
SUBMISSION BARCODE		
Date on Application		
Date of Application.		
EPA Received Date		
M Received Date		
The state of the s		
Assigned in PRAT, YESNO		
Completed by: S. Diana Budson Date		
	• • • • • • • • • • • • • • • • • • • •	
000000000000000000000000000000000000000	000000	9000000
FINAL ACTION		
LIMAL MOTION		**
Passance Code	- 1	•
Response Code		* * * * * * ***
Sponse Date: / /		
MOS:(1) Cite-All	No. of	
(4) Not Applicable		
(8) Selective		
CRP: Yes_ No		
Restricted Use: Yes No		



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

Bistechnologies for Hortisetture, Inc. 120 Zower Drive Bun Rilge, IL 60521

PRODUCT NAME: Lithylfloc COMPANY NAME: Biothologies for Hort, Sac.

OPP IDENTIFICATION NUMBER: 224973

EPA FILE SYMBOL: 7/297- R EPA RECEIPT DATE: 13-11/97

RECEIPT OF APPLICATION FOR A NEW REGISTRATION SUBJECT:

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for a new registration and it has passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

It you have any questions please contact Phil Hutton, freduct Manager 92, at (203) 308-8260.

Sincerely,

Front End Processing Staff Information Services Branch Information Resources & Services Division /NIFT MIFT

# Jess R. Martineau, Ph.D. Consultant Regulatory Affairs

10854 S. Green Ridge Drive Sandy, UT 84070 Phone (801) 572-4386 Fax (801) 523-0377

EMail Jesmartino @ AOL.COM

November 22, 1997

US EPA - Office of Pesticide Programs (7505C). 401 "M" Street, S.W. Washington, D.C. 20460

Subject: New active ingredient registration: 1-methylcyclopropene (MCP)

Accompanying this letter are the documents needed to apply for registration of the new plant growth regulator, 1-methylcyclopropene (MCP), trade name; EthylBloc<sup>TM</sup>. Only an end use product is being registered at this time. The active ingredient is 0.43% of the formulation, with 99.57% inerts. The inerts have been cleared under 40 CFR for use on growing or harvested crops.

Attached is a copy of correspondence wherein the Biopesticide and Pollution Prevention Division agreed to review MCP. Also attached is a copy of the minutes from our January 16, 1997 meeting, wherein we reached an agreement regarding the data requirements for MCP for both non-food use, and food-use. This application is for non-food use.

Attached you should find the following in support of this registration:

- Registration Application (Form 8570-1)
- . Confidential Statement of Formula (basic) (Form 8570-4)
- . Confidential Statement of Formula (alternate) (Form 8570-4)
- . Certification with Respect to Citation of Data (Form 8570-29)
- . Labeling (5 copies)
- . Documentation of acceptance for review by BPPD.
- . Copy of minutes from meeting at EPA on January 16, 1997.
- . Transmittal Document
- . Supporting Data

The data have been generated by Horticulture for Biotechnologies, Inc. Storage stability and corrosion characteristics studies are underway, and will be submitted upon completion. We would request a conditional registration, pending the submission of these studies.

Horticulture for Biotechnologies, Inc has no other registration action pending. Being a small company, they need this registration approved as soon as possible, and would greatly appreciate an expedited review.

Should you have any questions, please call me at (801) 572-4386.

Sincerely,

Jess R. Martineau, Ph.D.

Consultant for Biotechnologies for Horticulture

## Transmittal Document

# To Support the Registration of 1-Methylcyclopropene (MCP)

1. Product name:

EthylBloc™

- 2. EPA Registration Number:
- 3. Company Number:

4. Applicant's Name and Address:

Biotechnologies for Horticulture, Inc.

122 Tower Drive Burr Ridge, IL 60521\_

5. Name of Active Ingredient:

1-methylcyclopropene

6. Source of Data Satisfying Requirements: Complete data requirements generated and

submitted by Biotechnologies for

Horticulture, Inc.

## 151A.10 Product identification and disclosure of ingredients

REJ (QI)

Doc. 1. Daly, J. (1997) Product Identity and Disclosure of Ingredients for 1-Methylcyclopropene (MCP). Unpublished study prepared by

Biotechnologies for Horticulture, Inc. 59 p.

# 151A.11 Manufacturing process

44464701 Doc. 2. Daly, J. (1997) Manufacturing Method for 1-Methylcyclopropene (MCP). Unpublished study prepared by Biotechnologies for Horticulture, Inc. 20 p.

# 151A.12 Discussion of the-formation of unintentional ingredients

REJ (O2)

Doc. 3. Daly, J. (1997) Discussion of Unintentional Ingredients in EthylBloc: Methylcyclopropene (MCP). Unpublished study prepared by Biotechnologies for Horticulture, Inc. 34 p.

## 151A.13 Analysis of samples

Doc. 4. Kourelis, B. (1997) Preliminary Analysis of Samples of Methylcyclopropene. (MCP)... Unpublished study prepared by Biotechnologies for Horticulture, Inc. 12 p.

# 151A.15 Certification of Ingredient Limits

REJ (Φ3)

Doc. 5. Daly, J. (1997) Certification of Ingredient Limits for EthylBloc<sup>TM</sup>.

Unpublished study prepared by Biotechnologies for Horticulture, Inc. 4 p.

# 151A 16 Analytical Methods for certified limits

Doc. 6. Daly, J. (1997) Analytical Methods for Certified Limits of Methylcyclopropene (MCP). Unpublished study prepared by Biotechnologies for Horticulture, Inc. 14 p.

# 151A,17 Physical and Chemical Properties

Doc. 7. Bennick, J. (1997) Product Chemistry for Non-Combustible End-Use Solids. Final Report: Laboratory Study Number 3454-97. Unpublished study prepared by Stillmeadows, Inc. 12 p.

# 152A-10 Acute oral toxicity

Doc.8. Pfeifer, R.W. (1996) Acute Oral Toxicity Study: Product Identification: MCP. Final Report: Laboratory Study Number 96G-2085. Unpublished study prepared by Toxikon Corporation. 30 p.

# 152A-11 Acute dermal toxicity

Doc.9. Pfeifer, R.W. (1997) Acute Dermal Toxicity Study
(Single Exposure): Product Identification: MCP. Final Report: Laboratory
Study Number 96G-2086. Unpublished study prepared by Toxikon
Corporation. 34 p.

# 152A-12 Acute Inhalation toxicity

Doc. 10. Bennick, J. (1996) Acute Inhalation Toxicity Study in Rats. Final Report: Laboratory Study Number 333-97. Unpublished study prepared by Stillmeadows, Inc. 16 p.

Page 2

## 152A-13 Primary eye irritation

Doc.11. Prezioso, J.A. (1996) Primary Eye Irritation Study: Product Identification: MCP. Final Report: Laboratory Study Number 96G-2089. Unpublished study prepared by Toxikon Corporation. 39 p.

## 152A-14 Primary dermal irritation

Under the Hold of the Hold of

## 152A-15 Hypersensitivity

Doc.13. Pfiefer, R. W. (1996) Beuhler Sensitization Test: Product Identification: MCP. Final Report: Laboratory Study Number 96G-2087. Unpublished study prepared by Toxikon Corporation. 42 p.

#### 152A-16 Hypersensitivity incidents

Doc. 14. Daly, J. (1997) Hypersensitivity Incidents Report for Methylcyclopropene (MCP). Unpublished study prepared by Biotechnologies for Horticulture, Inc. 4 p.

# 152A-17 Studies to detect genotoxicity

9 Doc.15. Prezioso, J.A. (1996) Salmonella Typhimurium Revers
Mutation Assay. Product Identification: MCP). Final Report: Laboratory
Study Number 96G-2139. Unpublished study prepared by Toxikon Corp.
36 p.

Doc. 16. Cifone, M.A. (1997) Mutagenicity Test on MCP in the
L5178Y TK ± Mouse Lymphoma Forward Mutation Assay. Final Report:
Laboratory Study Number 18384-0-431. Unpublished study prepared by
Covance . 29 p.

Doc. 17. Ivett, J.L. (1997) Mutagenicity Test on MCP in an
In Vitro Mouse Micronucleus Assay. Final Report: Laboratory Study '
Number 18384-0-455. Unpublished study prepared by Covance . 42 p.

## Transmittal Document

To Support the Registration of 1-Methylcyclopropene (MCP) EthylBloc™ 1. Product name: 2. EPA Registration Number: 3. Company Number: 4. Applicant's Name and Address: Biotechnologies for Horticulture, Inc. 122 Tower Drive Burr Ridge, IL 60521 5. Name of Active Ingredient: 1-methylcyclopropene 6. Source of Data Satisfying Requirements: Complete data requirements generated and submitted by Biotechnologies for Horticulture, Inc. 151A.10 Product identification and disclosure of ingredients Doc. 1. Daly, J. (1997) Product Identity and Disclosure of Ingredients for 1-Methylcyclopropene (MCP). Unpublished study prepared by Biotechnologies for Horticulture, Inc. 59 p. 151A.11 Manufacturing process Doc. 2. Daly, J. (1997) Manufacturing Method for 1-Methylcyclopropene (MCP). Unpublished study prepared by Biotechnologies for Horticulture, Inc. 20 p.

> Doc. 3. Daly, J. (1997) Discussion of Unintentional Ingredients in EthylBloc: Methylcyclopropene (MCP). Unpublished study prepared by

Biotechnologies for Horticulture, Inc. 34 p.

151A.12 Discussion of the formation of unintentional ingredients

Page 1

	Doc. 11. Prezioso, J.A. (1996) Primary Eye Irritation Study: P	roduct
	Identification: MCP. Final Report: Laboratory Study Number 9	
	2089. Unpublished study prepared by Toxikon Corporation. 39	p.
52A-14 Primary	dermal irritation	
	Doc. 12. Pfiefer, R. W. (1996) Primary Dermal Irritation Study	: Product
	Identification: MCP. Final Report: Laboratory Study Number 9	
	2088. Unpublished study prepared by Toxikon Corporation. 33	p.
52A-15 Hyperso	ensitivity	
	Doc. 13. Pfiefer, R. W. (1996) Beuhler Sensitization Test: Prod	
	Identification: MCP. Final Report: Laboratory Study Number 9	
	2087.Unpublished study prepared by Toxikon Corporation. 42	p.
52A-16 Hyperse	ensitivity incidents	
•	Doc. 14. Daly, J. (1997) Hypersensitivity Incidents Report for	
	Methylcyclopropene (MCP). Unpublished study prepared by	
	Biotechnologies for Horticulture, Inc. 4 p.	
52A-17 Studies	Biotechnologies for Horticulture, Inc. 4 p. to detect genotoxicity	
52A-17 Studies	to detect genotoxicity	e
52A-17 Studies	to detect genotoxicity  Doc.15. Prezioso, J.A. (1996) Salmonella Typhimurium Revers	
52A-17 Studies	to detect genotoxicity	aboratory
52A-17 Studies	to detect genotoxicity  Doc. 15. Prezioso, J.A. (1996) Salmonella Typhimurium Revers Mutation Assay. Product Identification: MCP). Final Report: L	aboratory
52A-17 Studies	Doc. 15. Prezioso, J.A. (1996) Salmonella Typhimurium Reverse Mutation Assay. Product Identification: MCP). Final Report: L. Study Number 96G-2139. Unpublished study prepared by Toxis 36 p.  Doc. 16. Cifone, M.A. (1997) Mutagenicity Test on MCP in the	aboratory ikon Corp.
52A-17 Studies	<ul> <li>Doc. 15. Prezioso, J.A. (1996) Salmonella Typhimurium Reverse Mutation Assay. Product Identification: MCP). Final Report: L. Study Number 96G-2139. Unpublished study prepared by Toxi 36 p.</li> <li>Doc. 16. Cifone, M.A. (1997) Mutagenicity Test on MCP in the L5178Y TK ± Mouse Lymphoma Forward Mutation Assay. Final Reverse Matagenicity Test on MCP in the L5178Y TK ± Mouse Lymphoma Forward Mutation Assay. Final Reverse Matagenicity Test on MCP in the L5178Y TK ± Mouse Lymphoma Forward Mutation Assay.</li> </ul>	aboratory ikon Corp. ne nal Report:
52A-17 Studies	Doc. 15. Prezioso, J.A. (1996) Salmonella Typhimurium Reverse Mutation Assay. Product Identification: MCP). Final Report: L. Study Number 96G-2139. Unpublished study prepared by Toxis 36 p.  Doc. 16. Cifone, M.A. (1997) Mutagenicity Test on MCP in the	aboratory ikon Corp. ne nal Report:
52A-17 Studies	Doc. 15. Prezioso, J.A. (1996) Salmonella Typhimurium Reverse Mutation Assay. Product Identification: MCP). Final Report: L. Study Number 96G-2139. Unpublished study prepared by Toxis 36 p.  Doc. 16. Cifone, M.A. (1997) Mutagenicity Test on MCP in the L5178Y TK ± Mouse Lymphoma Forward Mutation Assay. Fin Laboratory Study Number 18384-0-431. Unpublished study presidents.	aboratory ikon Corp. ne nal Report:
52A-17 Studies	Doc. 15. Prezioso, J.A. (1996) Salmonella Typhimurium Reverse Mutation Assay. Product Identification: MCP). Final Report: L. Study Number 96G-2139. Unpublished study prepared by Toxis 36 p.  Doc. 16. Cifone, M.A. (1997) Mutagenicity Test on MCP in the L5178Y TK ± Mouse Lymphoma Forward Mutation Assay. Fit Laboratory Study Number 18384-0-431. Unpublished study prescovance. 29 p.	aboratory ikon Corp.  ne nal Report: epared by  Study
52A-17 Studies	Doc. 15. Prezioso, J.A. (1996) Salmonella Typhimurium Reverse Mutation Assay. Product Identification: MCP). Final Report: L. Study Number 96G-2139. Unpublished study prepared by Toxio 36 p.  Doc. 16. Cifone, M.A. (1997) Mutagenicity Test on MCP in the L5178Y TK ± Mouse Lymphoma Forward Mutation Assay. Final Laboratory Study Number 18384-0-431. Unpublished study prescovence. 29 p.  Doc. 17. Ivett, J.L. (1997) Mutagenicity Test on MCP in an In Vitro Mouse Micronucleus Assay. Final Report: Laboratory	aboratory ikon Corp.  ne nal Report: epared by  Study
52A-17 Studies	Doc. 15. Prezioso, J.A. (1996) Salmonella Typhimurium Reverse Mutation Assay. Product Identification: MCP). Final Report: L. Study Number 96G-2139. Unpublished study prepared by Toxio 36 p.  Doc. 16. Cifone, M.A. (1997) Mutagenicity Test on MCP in the L5178Y TK ± Mouse Lymphoma Forward Mutation Assay. Final Laboratory Study Number 18384-0-431. Unpublished study prescovence. 29 p.  Doc. 17. Ivett, J.L. (1997) Mutagenicity Test on MCP in an In Vitro Mouse Micronucleus Assay. Final Report: Laboratory	aboratory ikon Corp.  ne nal Report: epared by  Study

151A,13 Analys	is of samples	
	Doc. 4. Kourelis, B. (1997) Preliminary Analysis of Methylcyclopropene (MCP). Unpublished study pre Biotechnologies for Horticulture, Inc. 12 p.	•
151A.15 Certific	cation of Ingredient Limits	
	Doc. 5. Daly, J. (1997) Certification of Ingredient I Unpublished study prepared by Biotechnologies for	
151A.16 Analyt	tical Methods for certified limits	
	Doc. 6. Daly, J. (1997) Analytical Methods for Cer Methylcyclopropene (MCP). Unpublished study pre Biotechnologies for Horticulture, Inc. 14 p.	
151A.17 Physica	al and Chemical Properties	
	Doc. 7. Bennick, J. (1997) Product Chemistry for I Use Solids. Final Report: Laboratory Study Number study prepared by Stillmeadows, Inc. 12 p.	
152A-10 Acute	oral toxicity	
	Doc.8. Pfeifer, R.W. (1996) Acute Oral Toxicity S Identification: MCP. Final Report: Laboratory Stud 2085.Unpublished study prepared by Toxikon Corp	ly Number 96G-
152A-11 Acute	dermal toxicity	
	Doc.9. Pfeifer, R.W. (1997) Acute Dermal Toxicity (Single Exposure): Product Identification: MCP. Fit Study Number 96G-2086. Unpublished study prepartice Corporation. 34 p.	nal Report: Laboratory
152A-12 Acute ]	Inhalation toxicity	
	Doc. 10. Bennick, J. (1996) Acute Inhalation Toxic Final Report: Laboratory Study Number 333-97. Upprepared by Stillmeadows, Inc. 16 p.	

Page 2

# **EthylBloc**

EthylBloc is a powder that, when mixed with water or a buffering agent, releases a gas that can extend the life and usefulness of many fresh cut flowers, potted flowering, bedding, nursery and foliage plants. Crops are treated with this gas in enclosed areas such as rooms, coolers, greenhouses, truck trailers and shipping boxes/containers. This product is not intended for use outdoors or in other non enclosed areas.

Active Ingredient	(1-Methylcyclopropene)	0.43%
Inert Ingredients		99.57%
Total	200000000000000000000000000000000000000	100.00%

This product is not intended for use on food crops.

# CAUTION

See side panel for additional precautionary statements.

MFG. By BioTechnologies for Horticulture, Inc. 122 Tower Drive Burr Ridge, IL 60521 Made in U.S.A.

For product information: Call (800) 323-3689

EPA Est. No.
EPA reg. No
NET CONTENT: (25. 50. 100 or 200 gram units)



# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

## CAUTION

Causes moderate eye irritation.

Avoid contact with eyes or clothing.

Wear eye protection and gloves when handling this product.

Wash thoroughly with soap and water after handling.

Avoid prolonged breathing of vapors.

Do not take internally.

## STATEMENT OF PRACTICAL TREATMENT (FIRST AID)

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

#### **DIRECTIONS FOR USE**

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Read entire label before using this product.

For complete use directions, see accompanying Tech Sheet.

#### AGRICULTURAL USE REQUIREMENTS

Restricted re-entry - Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of four (4) hours. Treated area should be vented with outside air before reentry.

#### STORAGE AND DISPOSAL

#### STORAGE

Do not contaminate water, food, or feed by storage or disposal. Keep in closed container in a dry, cool place.

#### UNUSED PRODUCT DISPOSAL

Any residues generated that cannot be used according to label instructions may be disposed of through any normal sewer/septic system.

#### CONTAINER DISPOSAL

All container packaging may be disposed with normal trash.

#### CLEANING APPLICATION/MIXING EQUIPMENT

Wear a chemical-resistant apron and gloves.

#### TECH SHEET - COMPLETE DIRECTIONS FOR USE

EthylBloc® is sold as a powder that, when added to a Buffering Agent or water, then heated and/or agitated, releases a patented gas (1-Methylcyclopropene, MCP). When used properly, EthylBloc® can extend the life and usefulness of many fresh cut flowers, potted flowering, bedding, nursery and foliage plants. It works by inhibiting the negative effects of ethylene and thus prevents or reduces premature flower death, leaf and/or flower fall and leaf yellowing.

EthylBloc® was specifically designed to be used by all levels of the floral and nursery industries including growers, shippers, wholesalers, bouquet manufacturers, mail order houses and retailers (florist, garden center, nursery and mass market outlets). EthylBloc® is also very easy to use with almost no labor costs.

Some of the many flowers and plants that can often benefit from EthylBloc® treatment include:

Achillea, Aconitum, Agapanthus, Alchemilla, Allium, Alstroemeria, Alyssum, Aphelandra, Aquilegia, Asclepias, Astrantia, Asparagus Fern, Azalea, Begonia, Bouvardia, Brassaia (Schefflera), Brodiaea (Triteleia), Calathea, Campanula, Carnation, Celosia, Centaurea, Chamaedorea, Chelone, Coleus, Cordyline, Cymbidium, Crocosmia (Montbretia), Daucus (Queen-Annes-Lace), Delphinium, Dendrobium, Dianthus, Dicentra, Dizygotheca, Doronicum, Echium, Eremurus, Eustoma (Lisianthus), Ficus, Freesia, Fuchsia, Geranium, Gladiolus, Godetia, Gypsophila, Hibiscus, Ilex (Holly), Impatiens, Ixia, Kalanchoe, Kniphofia, Lavatera, Lily, Lysimachia, Miniature Carnation, Monkshood, Pelargonium, Petunia, Philodendron, Phlox, Physostegia, Poinsettia, Radermachera, Rose, Rudbeckia, Salvia, Saponaria, Scabiosa, Silene, Snapdragon, Solidaster, Stock, Streptocarpus, Sweet William, Trachelium, Trollius, Veronica, Wax Flower, and Zygocactus.

Crops must be exposed to this gas in enclosed areas such as greenhouses, rooms, coolers, shipping boxes or trailers. These enclosed areas should be fairly gas tight as excessive leakage will reduce EthylBloc® effectiveness. This product is not intended for use outdoors or in other non-enclosed areas.

EthylBloc® is more effective when crops are exposed to this gas for at least four hours under warm temperature conditions (55° to 75° F, 13° to 24° C). Higher dosages and longer treatment times are required for crops held under lower temperatures (below 55° F, 13° C) but the effectiveness should remain the same.

EthylBloc® can be used just prior to harvest, immediately after harvest, just prior to shipment, upon arrival from the supplier, and/or just prior to sale. To realize maximum benefits, all of the crops listed above should be treated regardless if they might have been already treated with EthylBloc® or with another anti-ethylene product at an earlier point in the distribution chain.

Shipments which have already been treated with EthylBloc® do not have to be retreated. However, as noted above, retreating is not harmful and can even be beneficial. Examples of some species that would likely benefit from additional applications include those with more than one flower per stem (i.e. snapdragons, delphiniums, miniature carnations and alstroemeria) and flowers at different stages of development on the same plant (i.e. geraniums, impatiens, and azaleas).

EthylBloc® comes with a scoop for easy measurement along with the proper Buffering (mixing) Agent. The Buffering Agent is used to facilitate MCP gas release from the white powdered carrier. It contains 0.75% potassium hydroxide and 0.75% sodium hydroxide after the proper amount of water is added. Users can substitute tap water for the Buffering Agent but the MCP gas release will likely not be as efficient. Using warm water and/or continuous agitation after mixing is best, if the Buffering Agent is not used. Contact the manufacturer for additional mixing tips, if water, not Buffering Agent, is used. Refer to the information presented below for selecting the right number of EthylBloc® scoops and Buffering Agent volume for your application.

#### APPLICATION IN GREENHOUSES PRIOR TO HARVEST

Fresh cut flowers and bedding, potted flowering, nursery and foliage plants can be treated in the greenhouse just prior to being harvested.

To treat with EthylBloc®:

- 1. The greenhouse must be tightly constructed. Plastic covered houses (especially double poly) are generally tighter than fiberglass or glass covered ones.
- 2. Sections of greenhouses can be enclosed with plastic to make the treatment area smaller as long as it is sealed properly to prevent the gas from escaping.
- 3. Make sure all greenhouse vents are closed. Night treatment is recommended mainly because vent closing is more realistic and treatment times can be longer.
- 4. Any internal air circulation system (that does not bring in outside air) should remain on during treatment to help distribute the gas.
- 5. The amount of EthylBloc® required depends on the volume of the greenhouse, treatment temperature, and treatment time.
- 6. To determine the approximate greenhouse volume, multiply the greenhouse width x length x ½ of the height measured at the ridge/peak. For example, if a greenhouse is 25 feet wide x 100 feet long x 10 feet high, the approximate volume equals 25 x 100 x 10/2 = 12,500 cubic feet.
- 7. The above described calculations can also be done in meters, as dosages are presented both in per cubic foot and per cubic meter.
- 8. All greenhouse treatments should be done at temperatures greater than 55° F, 13° C.
- 9. For treatment times from four to eight hours, the correct EthylBloc® dosage is one scoop per 100 cubic feet or one scoop per 3.0 cubic meters.

Note: One level scoop equals about 1.5 grams

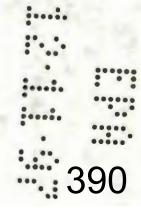
- 10. For treatment times from 12 to 16 hours, the correct EthylBloc® dosage is reduced to one scoop per 200 cubic feet or one scoop per 6.0 cubic meters.
- 11. The correct amount of Buffering Agent to use is one ounce (about 30 ml) per scoop of EthylBloc®.

- 12. The mixing container should be made out of plastic and be large enough to hold the EthylBloc® and Buffering Agent. A plastic pail works well for larger applications while a plastic bowl or similar container for smaller applications.
- 13. Please refer to *Tables One, Two and Three* for examples of recommended EthylBloc<sup>®</sup> dosages based on room size, treatment temperature and treatment time.

#### 14. To mix:

- a. First add the proper amount of EthylBloc® to the mixing container.
- b. Then add the proper amount of Buffering Agent, making sure that all of the EthylBloc® powder is covered. Warm water is better than cold water.
- c. Briefly stir the mixture for about 5 to 10 seconds and then leave the treatment area, making sure the area is properly sealed behind you. Providing for continuous agitation or heat is best.
- 15. Disposal of the remaining mixing solution can be made in normal septic or sewer systems.

Restricted re-entry - Do not enter or allow worker entry into treated greenhouses during the restricted-entry interval (REI) of four hours. Treated greenhouses should be vented with outside air before re-entry.



# APPLICATION IN HOLDING/STORAGE ROOMS, COOLERS, TRUCK TRAILERS AND OTHER ENCLOSED AREAS

Non-boxed crops being held in enclosed areas can be easily treated with EthylBloc<sup>®</sup>. For example, sleeved potted plants and cut flowers (held dry or in solution) that are not boxed can be treated. Boxed plants and cut flowers with the lids and/or precooling vents completely open can also be treated as long as the box openings are directly exposed to the surrounding atmosphere and thus the EthylBloc<sup>®</sup> gas. Bedding or potted plants on movable racks are easily treated.

Examples of typical areas that could be used for treating crops with EthylBloc® include:

- Retail florist coolers including walk-in, storage and/or walk-in/storage combinations.
- Wholesale florist coolers.
- Delivery trucks or vans, regardless of their size/volume.
- Truck trailers.
- Inter-modal containers.
- Any room in a building that could be isolated, sealed and aerated/vented after treatment.
- Boxed crops if the boxes were enclosed in plastic such as being shrink wrapped.

Note: Some of the treatment area examples presented above may require plastic liners, tape and/or other products and procedures to make them more gas tight.

To treat with EthylBloc®:

- 1. Measure the size of the room/cooler/trailer (length, width, and height) in feet or meters.
- 2. Multiply these three numbers together to obtain the volume of the room in cubic feet or cubic meters.
- 3. Refer to Tables One and Two for the EthylBloc® rates if the treatment room and products are 55° F (13° C) or higher.
- 4. If the treatment and/or product temperature is below 55° F (13° C), the correct EthylBloc® dosage is three scoops per 100 cubic feet and three scoops per 3.0 cubic meters (see Table Three).

5.

- 5. The mixing container should be made out of plastic and be large enough to hold the EthylBloc® and Buffering Agent. A plastic pail works well for larger applications while a plastic bowl or similar container for smaller applications.
- 6. Please refer to all three *Tables* for examples of the recommended rates based on treatment temperatures and time.

#### 7. To mix:

- a. First add the proper amount of EthylBloc® to the mixing container.
- b. Then add the proper amount of Buffering Agent or water, making sure that all of the EthylBloc® powder is covered. Warm water is better than cold water.
- c. Briefly stir the mixture for about 5 to 10 seconds and then leave the treatment area, making sure the area is properly sealed behind you. Providing for continuous agitation or heat is best.
- 8. Disposal of the remaining Buffering Agent can be made in normal septic or sewer systems.

Restricted re-entry - Do not enter or allow worker entry into treated greenhouses during the restricted-entry interval (REI) of four hours. Treated greenhouses should be vented with outside air before reentry.



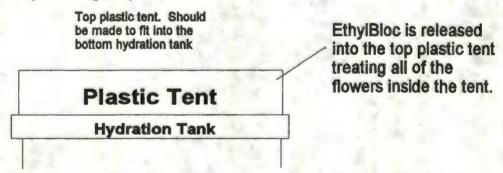
#### APPLICATION IN AREAS SPECIFICALLY BUILT FOR ETHYLBLOC® TREATMENT

General EthylBloc® Treatment Chamber. It might be appropriate to construct an area to be used solely for EthylBloc® treatment. By doing so one can maximize the EthylBloc effectiveness and reduce costs by requiring less EthylBloc® to treat a given number of crop units.

While this treatment area could be built using a number of gas impermeable materials, 4.0 to 6.0 mil polyethylene should work well. Just make sure the unit is sealed properly.

One way to help ensure a good seal where the plastic comes in contact with the floor is to use water. Namely, the base (plastic) of the treatment unit is submerged in a trough of water a few inches deep thus making a good seal where gas cannot escape.

To use such a treatment area, follow the same directions presented above for greenhouses and other enclosed areas making sure you adjust the rates based on crop and room temperatures. Constructing such specific EthylBloc® treatment areas has proven to be an effective way of using EthylBloc®.



Bottom tank is about 15-20cm high and full of solution. The flowers sit in this solution and hydrate while being treated with MCP

Cut flower: Hydration/EthylBloc® Treatment Chamber. The top of the chamber can be made of 4.0 to 6.0 mil polyethylene and a wooden frame, a single plastic piece that can fit into the bottom hydration tank, or something similar. The bottom tank can be any size tub that is capable of holding solutions. See drawing above.

Place the flowers into the bottom tank in bunches or buckets. Place the top plastic tent over the bottom holding tank. The tent's bottom edges must be able to be submerged into the solution to the bottom of the tank to insure a seal. Lift an end of the tent up and place the bowl or bucket containing EthylBloc® powder into the chamber. Place the Buffering Agent into the bowl or bucket, totally covering the powder. The contents in the bowl/bucket must remain separate from the solution in the tank throughout the treatment. Immediately seal the tent by submerging the walls of the tent in the solution to the bottom of the tank. Follow EthylBloc® use directions already presented.

Table One: EthylBloc® and Buffering Agent rates based on treatment temperatures being at least 55° F (13° C) and treatment time be a minimum of four and up to eight hours in various room sizes. Rates not given can be calculated by combining treatment room sizes.

TREA	TMENT ROOM SIZ	ZE ETHY	ETHYLBLOC®		<b>Buffering Agent</b>	
cubic feet	cubic meters	scoops	grams	ounces	milliliters	
100	3	1	1.5	1	30	
500	15	5	7.5	5	150	
1000	30	10	15.0	10	300	
2500	75	25	37.5	25	750	
5000	150	50	75.0	50	1500	
10000	300	100	150.0	100	3000	

Note: A minimum four hour exposure is required. Overnight exposure (eight hours) is even better.

**Table Two**: EthylBloc® and Buffering Agent rates based on treatment temperatures being at least 55° F (13° C) and treatment time be a minimum of 12 to 16 hours in various room sizes. Rates not given can be calculated by combining treatment room sizes.

TREA	TMENT ROOM S	IZE ET	ETHYLBLOC®		Buffering Agent	
cubic feet	cubic meters	scoops	grams	ounces	milliliters	
200	6	1	1.5	1	30	
1000	30	5	7.5	5	150	
2000	60	10	15.0	10	300	
5000	150	25	37.5	25	750	
10000	300	50	75.0	50	1500	
20000	600	100	150.0	100	3000	

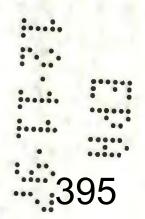
Note: A minimum 12 to 16 hour exposure is required.

**Table Three:** EthylBloc® and Buffering Agent rates based on treatment temperatures being between 35° and 55° F (3° and 13° C) and treatment time be a minimum of 10 hours in various room sizes. Rates not given can be calculated by combining treatment room sizes.

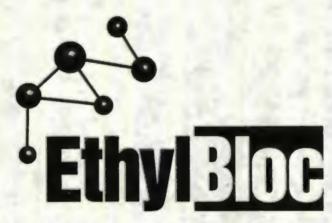
TREA	TMENT ROOM S	IZE ET	HYLBLOC®	<b>Buffering Agent</b>				
cubic feet	cubic meters	scoops	grams	ounces	milliliters			
100	3	1.5	2.3	1.5	45			
500	15	7.5	11.3	7.5	225			
1000	30	15.0	22.5	15.0	450			
2500	75	37.5	56.3	37.5	1125			
5000	150	75.0	112.5	75.0	2250			
10000	300	150.0	225.0	150.0	4500			

<sup>\*</sup> Note: a minimum 10 hour exposure period is required for plants and flowers being held at 55° F (13° C) or lower. Longer exposures are even better.

Contact BioTechnologies for Horticulture if questions arise at (800) 323-3689 (630) 325-1888



# (EthylBloc Powder Outer Carton Label)



This product is not intended for use on food crops.

Este producto no debe utilizarse en cultivos destinados a fines de alimentación.

Active Ingredient	(	1	Ą	A	sŧ	h	y	k	:y	C	de	ķ	ÞΓ	o	p	•	n	8	) .			,	 . ,	0.43	%
Inert Ingredients .														4			٠		•	6	0	۰		99.57	%
Total				n							٠										,		1	00.00	%

## Ingrediente activo (1-Metilciclopropeno) . . . . . . 0,43%

# KEEP OUT OF REACH OF CHILDREN

# CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear eye protection and gloves when handling this product. Wash thoroughly with soap and water after handling. Avoid prolonged breathing of vapors. Do not take internally.

STATEMENT OF PRACTICAL TREATMENT (FIRST AID)

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.



# **BioTechnologies** for Horticulture, Inc.

122 Tower Drive Burr Ridge, IL 60521 Mfd. in U.S.A.

For product information: Call (630) 325-1888

(NET CONTENTS: 100 grams)

# MANTENGA FUERA DEL ALCANCE DE LOS NIÑOS CUIDADO

Causa una irritación moderada a los ojos. Evite el contacto con los ojos o la ropa. Protéjase la vista y use guantes cuando manipule este producto. Lávese totalmente con agua y jabón después de la manipulación. Evite respirar los vapores por un tiempo prolongado. No ingiera el producto.

DECLARACION DE TRATAMIENTO PRACTICO (PRIMEROS AUXILIOS)

SI PENETRA EN LOS OJOS: Lávese los ojos con abundante agua. Llame a un médico si persiste la irritación.



FABR. por

# **BioTechnologies** for Horticulture. Inc.

122 Tower Drive Burr Ridge, IL 60521 Hecho en EE.UU.

Para información del producto: Liamar al (630) 325-1888

(CONTENIDO NETO: 100 g)



January 27, 1997

Dr. Robert Torla
Office of Pesticide Programs
U.S. EPA (H7503W)
Washington, DC 20460

Via Fax (703) 308-7026

Dear Dr. Torla.

Thank you, Cheryl, Tom and Fresteh for an excellent meeting. As requested, here are minutes from the meeting as I composed them.

Date of Meeting: January 16, 1997
Subject: Registration of MCP

Present: Bol

Bob Torla, Cheryl Reilly, Fresteh Toghral, Tom McClintock,

George Staby, Richard Basel, Jess Martineau

George gave a brief summary of MCP. The mode of action is to inhibit ethylene. The proposed use sites are ornamentals (cut flowers) and stored fruits and vegetables. Only an end use will be registered. Two separate registrations will be sought; one for ornamentals and one for food crops. The formulation is a powder which produces a gas when it comes in contact with water. The carrier is

. MCP has previously been reviewed and the decision made that it would be reviewed by BPPD with reduced requirements.

George illustrated the very low dose rates (6 grams) of MCP required to treat a complete commercial container (3,500 cubic feet). When used at the recommended rate, the concentration of MCP is below the limit of detection.

Richard discussed the analytical methods, with input from Fresteh. Two analytical methods are requested. George discussed the specificity of the receptor sites in plant material. Fresteh pointed out the value of showing that animals do not have receptor sites for MCP. Such evidence would be useful in justifying waivers for subchronic studies and also to support a petition for the exemption from the requirement of a residue tolerance.

Cheryl discussed the FQPA, and provided draft copies of the form to be used. George asked if she could share a completed example, to which she agreed.

Jess discussed the results of the acute toxicity studies completed to date, to wit;

Acute oral toxicity - limit
Acute dermal toxicity - limit
Primary eye irritation - Cat. III
Primary skin irritation - non-irritant

Dermal sensitization - non-sensitizer Ames - negative

Further requirements were discussed. The need for an acute inhalation study was pointed out. Fresteh recommended a whole animal study, using the gas form, at the highest concentration achievable. Richard pointed out that the gas becomes an explosive hazard at high concentrations.

Toxicology: In addition to the studies already conducted, 2 genotox studies will be required, in addition to the acute inhalation. Waivers will be requested for subchronic studies.

Product Chemistry: Studies to determine color, physical state, and odor will not be conducted per se, but these attributes mentioned elsewhere. Density, pH, storage stability and corrosion characteristics will be reported for the end product. Waivers will be requested for vapor pressure and octanol/water partitioning coefficient.

The analytical confirmation of MCP during processing, in the final products, and use were discussed. It was agreed that gas chromatography/flame ionization detection will be used to analyze samples. A backup, secondary method of gas chromatography/chemical ionization mass spectroscopy will also be used. The limit of detection will be shown by running samples at various concentrations. The correlation between the concentration at different concentrations will confirm good linearity of the detection method over a wide range of concentrations.

The methods will also be used to measure the concentration of the standards used for GLP studies. Proton Nuclear Resonance Spectroscopy along with GC/MS will be used to confirm the chemical identity of the MCP produced as standards.

Review time was discuss, and Bob indicated that less than a year is possible, but "no promises". Ornamental use approval would be quicker than for food use, due to fewer data requirements.

Re-entry requirements were discussed. A 4 or a 6 hour re-entry may be possible, given low/no toxicity, low dose rates, and if it can be shown that animals/humans have no receptor sites.

Again, thank you for taking the time to meet with us. If I missed anything in the minutes, please let me know.

Sincerely,

Jess R. Martineau cc: George Staby



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

April 17, 1997

Jess R. Martineau, Ph.D. 10854 S. Green Ridge Drive Sandy, UT 84070

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Dear Dr. Martineau;

The attached printout from our biochemical classification database should serve to show the decision process for MCP. The BPPD Division Director, Janet Andersen, has signed off on reviewing MCP in the Biopesticide and Pollution Prevention Division.

Sincerely,

William R. Schneider, Ph.D., Chair Biochemical Classification Committee

Biopesticide & Pollution Prevention Division (7501 W)

Product Reviewer: William Schneider Date of initial draft review 07/29/96 10:38:52 AM

Date reviewed by the Classification Committee 12/03/96

Product Name/ Active ingredients: 1-methylcyclop:opene.

Company: Perishables Research Organization Address: PC Box 1552 Healdsburg, CA 95448

Company contact: George L. Staby, Ph.D., President

Phone: 707-433-1982 FAX number: 707-433-1984 eMaii: stabygeo@aol.com

Company Representative: Address:

Phone: FAX number: eMsil:

Use Parterns: This is a gas that is used for treatment of fruits and regetables to delay ripening. It temporarily blocks the formation of ethylene. One short treatment will last for 3 weeks.

The activity of this product indicates that it is a Plant Growth Regularor

Natural Occurrence: It will be synthesized so it will have to be structurally similar and functionally identical to a naturally-occurring chemical. The company cites various literature that states, that cyclopropane and cyclopropene acids are produced by the plant family Malvaceae, ".... certain fatty acids contained a cyclopropene system ...", cyclopropane fatty acids are found in some microbial pathways, chrysanthemic acid (from pyrethrine) has a cyclopropane ring, and ethylene biosynthesis involves a cyclopropane derivative,

1-amino-2-methyl-cyclopropane-1-carboxyllc acid. The two references cited to support cyclopropene acids occuring in plants reported investigations of the synthetic pathways of sterculic acid (found in Sterculia foetida - indian aimond) and melvalic acid (long chain fatty acids containing a cyclopropene ring). The ring structure was theorized to be formed by activity on the long chain and not involving a separate ring formation process. Note that we have no references for the natural occurence of 1-MCP itself - (as a gas it would probably be a very transient, reactive, intermediate).

Mode of Action: The mode of action is growth regulation and is a non-toxic mode of action.

Decision: This gas has not been shown to occur naturally. The committee recognizes that, as a gas, it is difficult to determine if this is a naturally-occurring substance. However, it can not be proved to fit the biochemical pesticide definition. The use of MCP as a growth regulator does fit the other characteristics of a biochemical pesticide, e.g. growth regulation, low use rates (it is effective in ppb amounts), non-persistence and non-toxic mode of action. An analysis of MCP was performed by the OPPT Structure Activity Team. The analysis suggested that the tiered system data set used for biochemical pesticides would be appropriate for risk assessment of MCP. The committee agreed that MCP would be eligible for review using a reduced data set similar to that used for biochemical pesticides and could be considered for review by BPPD.

Committee	Classification:	Not a	Biochemical	JUT	aligibie	tor	raducad	data	set	•
										•
										•
	******************	4 * * * * * * * *			*********		• • • • • • • • • • • • • • • • • • • •			
									-	_



NIFT	reverse before comple	ting form.	* Form	n Annrovec	1. OMB No. 207	0-0060	Approval expires 2-28-9			
<b>≎EPA</b>	Environmental Washi	on Agency	X	Registration Amendme Other	on	OPP Identifier Number 224973				
		Application	on for Pesticide - S	Section						
. Company/Product Number	71277-	R	2. EPA Product Robert T PM#			3. Pro	None Restricted			
Brotechnologies 120 Town in Bun Ridge,	plicant Include ZIP Co for Hotticuli drive IL 60521	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No.								
Check if this	s is e new address		Product Nar	me						
			Section - II							
Amendment - Explain Resubmission in res	n below. conse to Agency letter	dated	Ageno	Final printed lebels in response to Agency letter dated "Me Too" Application.						
Notification - Explain	below.		Other	- Explein b	elow.					
. Material This Product Wi	Il Be Packaged in:		Section - III							
child-Resistant Packeging Yes* No	Unit Packaging Yes No	Water Soluble Packagin Yes No	ng	X P	ntainer Aetel Yastic Glass					
Certification must e submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" No. Package wgt con	aper Other (S	er (Specify)					
Label	Information Container		tail Container	-	On Lebel On Labeling		ons panying product			
. Manner in Which Label is	Affixed to Product	Lithog Paper Stenc	glued iled	Other						
			Section - IV							
1	items directly below	for identification	on of individual to be conta	cted, if ne	Y	_	******			
dess R.	Martineau		Consultant		1		e No. (Include Aree Code)			
	ny knowingly felse or i		ation I all ettechments thereto er tement may be punishable			ete.	6. Date Application Received (Stamped)			
. Signature X	7		3. Title Vice Presid		•					
. Typed Name  Jm Daly		5. Date 9/25/97		••••						

#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Ragulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First detarmine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will eppear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration.

  The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to axisting registrations, that are similar or identical to other posticide products that ere currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a sita, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "genegal label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packafing Check the appropriate block if your product will be packaged in the indicated packaging types.
- Indicate the size of the individual packets and number par retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Marmer in which label is affixed to product indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," registration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95

**\$EPA** 

**United States** 

# Environmental Protection Agency Washington, DC 20460

X	Registration
	Amendment
	Other

**OPP Identifier Number** 

224973

Other									
	Application for	Pesticide - Section	1	and the second second					
1. Company/Product Number	R	2, EPA Product Manager	3. Proposed Classification						
4. Company/Product (Name)		PM#	None Restricted						
5. Name and Address of Applicant (Include ZIP Control of Applicant (Includ	ode)	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No.  Product Name							
	Sec	tion - II							
Amendment - Explain below.  Resubmission in response to Agency lette  Notification - Explain below.		Final printed labels in response to Agency letter dated "Me Too" Application.  Other - Explain below.							
Parlanda and an analysis of the			1007	~~					
Explanation: Use additional page(s) if necessary. (For section I and Section II.)									
	Sec	tion - III							
1. Material This Product Will Be Packaged In:									
Child-Resistant Packaging  Yes  No  * Certification must be submitted  Unit Packaging  Yes  No  Unit Packaging  Unit Packaging  Yes  No	No. per If "Ye	Yes No  No. per container	Gla Par	tal Büc 88					
3. Location of Net Contents Information  Label Container	4. Size(s) Retail Conta		Cation of Label Dir On Label On Labeling a	rections					
6. Manner in Which Label is Affixed to Product	Lithograph Paper glued Stenciled	Other							
	Sec	tion - IV							
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)									
Name Jess @ Martines	Title	mse (tat		phone No. (Include Area Code)					
Certification I certify that the statements I have made on this form and all attachments thereto ere true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.  6. Date Application  (Stamped)									
2. Signature A		e President							
4. Typed Name	5. Date	25/97							

#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS



PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to everage 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmantal Protaction Agency, 401 M Street, SW, Washington, DC 20460; and to the Offica of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use raregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all epplications for new ragistration. Such draft labels my in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Ragistration actions, Sections I, Ill, and IV must be completed by the applicant. For applications submitted in connection with amended reragistration actions, rasubmissions, notifications, reregistrations, etc., Sections i, ii, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

SECTION ! - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you es a basic registrant, a distributor, or as an establishment. If your product is registered, insert tha Product Number.
- EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- Proposed Classification Specify the proposed classification of this product.
- Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not parmitted among products of the same company. Do not include any brand name or company line designations,
- 5. Name and Address of Applicant The name of the firm or person end address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for tham in registra matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name end complete mailing address of such an agent must accompany this application.
- Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currantly ragistered product (Amendment), for a resubmission in response to an Agency lattar, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for

1. Subject of submission - Chack the applicable block end provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach e separata page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Peckaging - Check the appropriete block if your product will be packaged in the indicated packaging types.

- Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Lecetion of Net Confents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.

  5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Consect Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too, " ceregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

**United States** 

#### **Environmental** Protection Agency

Washington, DC 20460

Form Approved OMB No. 2070-0060 Approval Expires 02-28-95

Certification with Respect to Citation of Data

**EPA File Symbol/Registration Number** Applicants Name and Address BioTechnologies for Horticulture, Inc Methyl cyclo propere (mcp) **Product Name** 120 Tower Drive Burt Ribge, IL 60521 Date of Application october, 1997

NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

- 1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.)
- 2. I certify that, for each study cited in support of this application for registration that is an exclusive use study. I am the original submitter\*; or I have obtained the written permission of the original submitter for which is (for 'multiple chemicals link the companies who are original data submitters (insert names of companies) with the appropriate chemical name) to cite that study\* 3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study; I am the original data submitter\*; or I have obtained the written permission of the original data submitter for which is (insert name of chemical) (for multiple chemicals link the companies who are original data submitters (insert names of companies) with the appropriate chemical name) to cite that study\*; or I have notified in writing the companies that (insert names of companies) (insert name of chemical) have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (for multiple Companies (insert name of chemical) (insert names of companies) chemicals link the companies who are original data submitters with the appropriate chemical name) listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method\*). (Also, sign the General Offer Statement below.) Companies (for multiple (insert names of companies) (insert name of chemical) chemicals link the companies who are original data submitters with the appropriate chemical name) that have submitted the studies which I have cited (Selective method\*). I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired.

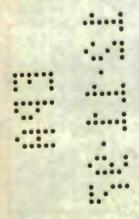
* A	Data Matrix i	dentifying these studies is attache	ed. (Note: a Data Matrix is	not required under the cite	-all method)
Signature X	1	Name and Title	President	Date 9/25	192
	16	General Offer to Pay: I hereby offer regard to the approval of this applica	and agree to pay compensation to		
Signature V	11	Name and Title	0 1 -	Date 9/	-/000

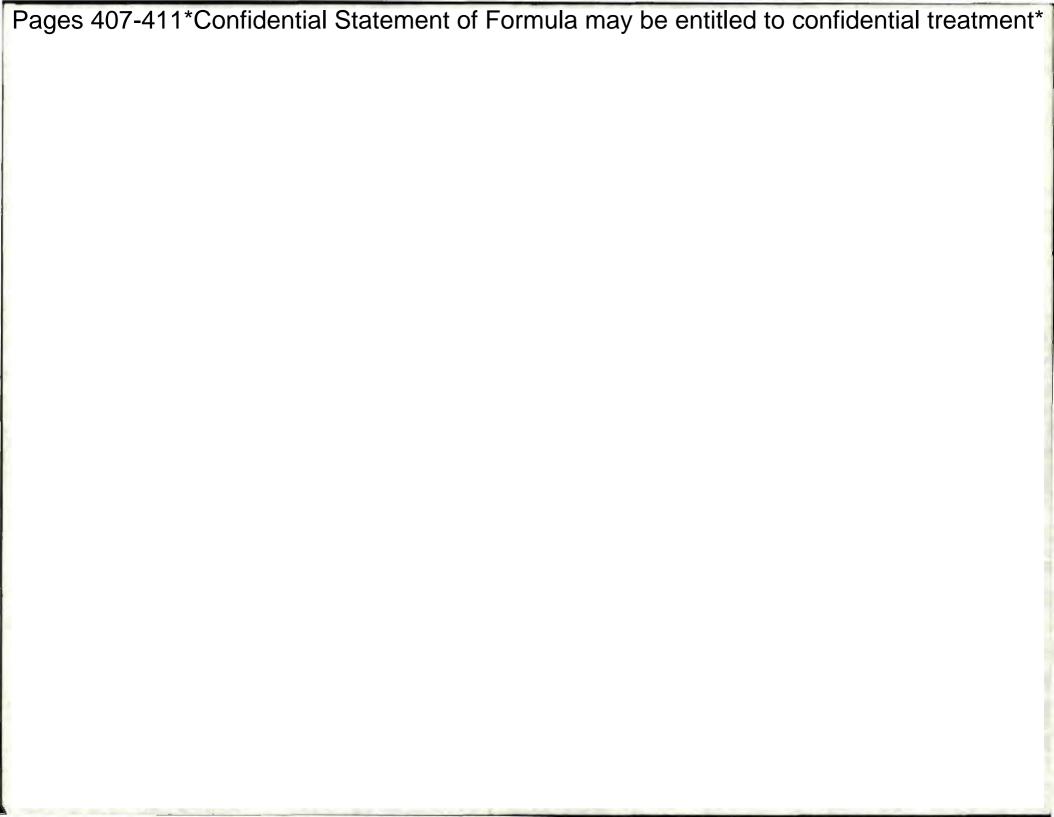
President

(Rev. 5-94) Electronic and Paper versions EPA Form acceptable.

#### Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 2.5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining needed data, and completing and reviewing this application form. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M Street, S. W., Washington, DC 20460; and to Office of Management and Budget, Paperwork Reduction Project (2070-0055), Washington, DC 20503, marked "Attention Desk Officer for EPA."





Called Bot Lauhin

215104 - Lefst Voice Marl

told him this CSF (Lattest

of record) - had wrong

prod-name! Ethyl Bloc

prod-name! Ethyl Bloc

is correct nowe + needs

andt. SKR

